Hikma 2025 US Meet the Management Transcript (edited)

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Hikma Rx

Speakers:

Hafrun Fridriksdottir	*President, Hikma Rx*
Kristy Ronco	*Chief Commercial Officer, Hikma Rx*
Chris Edlin	*VP R&D, Hikma Rx*
Brett Bukvic	*AVP BD & Product Selection, Hikma Rx*
Tyson Ardo	*AVP Quality, Hikma Rx*
Mike Balog	*SVP Operations, Hikma Rx*

Hafrun Fridriksdottir: My name is Hafrun Fridriksdottir, for those who I have not met formally. I've been with Hikma, slightly more than one year. I started in April last year. My background is that I'm a pharmacist with a PhD in physical pharmacy. I've been in the industry for more than 30 years. I sometimes say 35, of course, it always depends on how you count things. Almost most of my career, almost all my career in R&D, in multiple companies, started in a small company called Omega Pharma, then Actavis, Watson, back to Actavis, Allergan, Teva. I was, six years as head of R&D for Teva. Then I left Teva went over to a small biotech company. Alvotech in Iceland. And then I came over to Hikma. So very happy to be here. It's, Of course, a very good team, which I have here on the left hand side.

I'm very proud of the team. And just to say that I have been involved in developing all kinds of products in my career, both ANDA filings, biosimilars and, and novel products as well. But I wanted to start with, allowing my team to introduce themselves and talk a little bit about their background. And, who wants to start? Mike, you have talked so much the whole morning, so maybe you start with Kristy.

Kristy Ronco: Good afternoon everyone. For those of you, I didn't have the privilege of meeting yesterday or this morning. My name is Kristy Ronco and I am the chief commercial officer for the US, generics business. I have, more than 25 years in the U.S. pharma industry. Across both brand and generics segments. I lead our sales and marketing efforts for our non-injectable products. And happy to lead our U.S., shared service commercial operations, from an order to cash perspective. So, pleasure to be here today.

Chris Edlin: Yeah. Hi. My name is Chris Edlin. I'm the VP of R&D. My background's in chemistry, so I have a degree and PhD in synthetic organic chemistry. I've worked for GSK, Roche and then most recently I spent the last seven years with Teva leading various respiratory CMC activities.

Brett Bukvic: My name is Brett Bukvic. I run business development and product selection for Hikma's, generics business. Now, Hikma Rx. I've been here for about a decade. So all inorganic and organic products that go into our pipeline goes through my team is kind of the central coordinator of those evaluations, and I was at Baxter Healthcare before this.

Mike Balog: I'm going last.

Tyson Ardo: So. Okay, so I'm Tyson Ardo, I'm the head of quality for the generics division, and I have been at this site for a little over 19 years.

Mike Balog: So I met a few of you, Mike Balog, senior vice president, general manager of Columbus Operations. Been with the organization, eight years. Prior to that, I was with Teva. I ran two facilities for them. The largest generics player. I'm sure you guys know. Prior to that proud veteran, I was in the Navy for eight years on submarines. Nuclear engineering background.

Hafrun Fridriksdottir: Oh, course. Of course. Brett managed to steal my thunder because I was coming out with a big announcement at this time in the presentation. It was. It was all rehearsed. You know, that was all rehearsed. And so. So we are changing the name of the of the generic division from now on to Hikma Rx and so, so why are we doing this? I mean, one of the reasons for why we are doing this is that, it has been some kind of a negative, negative steam around Hikma Generics. And I think people have understood the name in such a way that we only produce simple, simple tablets, simple capsules, and only simple products. But of course, as you have seen today, that's not what we do.

So the majority of the value of the product which we sell our complex product. Well, you saw the usual fluticasone line. You saw the Advair line. And, and so you saw many of the lines with which we are producing those complex products on. And we also feel that, Hikma Rx better reflects the focus on that we are providing differentiated and complex, prescription products.

So that's, that's the reason for it. And just to say that as well, that 60% of our income for this division are from complex products. And so, so why Columbus? Why are we here? The reason is that this site was acquired from BI in 2016 and this building was built in 1987. And, so this building is, yeah, more than more than 30 years old and sstill in a very good shape as, as you, as you saw. Around 50% of all of the people which we have here or here in US are located in this building.

Both, operational and also the headquarters. We are the second largest employer in Columbus. And we are very, very proud of that. We believe that we are number ten, of volume, as a manufacturer for generic products here in the US and probably around number five for solid oral. And, we also talked about that when we, at least in the, in the group, which I was in when we were taking the tour, that, our plan is to spend around $500 million over the next five years, both on expanding our CMO business, but also, to strengthen our internal, capabilities for our internal programs.

So, so there's a lot of activity, a lot of things going on. And, of course, you will see more of that when we go when my team, goes through their presentations. So what are we going to cover today? Mike will talk about manufacturing. Chris and Brett will talk about, R&D and business development. Kristy will talk about commercial, and, Tyson, I forgot you. You will be part of the manufacturing section. I never forget you. So so he will be taking part in the manufacturing presentation. And then, of course, we, have a wrap up. So we would prefer if we if you keep all your questions until of course, later. Later in the afternoon, after the injectable team has presented their part of the of the agenda as well. Except if there is something really, really burning, then of course we will not stop you. So let's talk about how we fit, how it fits in the family, as you know, there are those three divisions. Hikma Rx, Hikma injectables and the, MENA or the branded business.

So we are responsible for, 33% of the revenue or this is from last year and, 21% of the of the core operating profits of, of course, we want to do much better. And that's, of course, why we are talking about all those expansions, today, both in the CMO business, but also in our internal pipeline, 90% of the product which we are selling from this division are produced here at the site. So, so 90% of the value. So, so that's, quite, of course, significant.

So what does Hikma Rx stands for? It stands for very, talented people. And, we have we have a lot of capacity as I mentioned earlier, at the site, we have, we have a strong R&D, team and, we are we are, of course, expanding that. Chris just started as a head of head of R&D, a few months ago.

We are also utilizing other capabilities within the company to support our R&D growth. We started, I think, nine new products last year, and then we added a number of business

development opportunities into our pipeline as well. We believe that there is a benefit or, or quite a big benefit of being having a majority of our US manufacturing done here in US with all the discussion which is happening, happening around tariffs.

We have an excellent, FDA track record. And Tyson will talk a little bit more about that later. And then, of course, we have a deep industry experience and and strong customer focus. I think, last year we received the almost the highest score from our customers and service level. And that's something which was not only last year, but, has been, has been the trend over the over number of years.

Kristy can speak more to that later. So I don't know if any of you were here at a similar meeting in 2021. If so, raise your hand. But probably none. None of this group. But I think there was a similar meeting to this in in 2021 when we talked about how we are going to grow the business, what our focus will be on moving forward.

And, we identified both inorganic and organic growth. So one of the focus, and clearly there is a lot of things which have happened since, since then, we have have been focusing on, developing a new product internally, acquiring high value ANDAs, and also signing a signing contract with the, CMO partners. And we have been focusing on selecting our partners, quite carefully focusing on, on, branded companies, and, maybe trying to be, be very selective when, when we are, choosing our partners, for the CMO business.

And you have probably heard that there is a lot of there is a lot of opportunities, in that area now with, with the tariffs and there's a lot of discussion from our competitors. They all want to build the new capability, new capacity here in the US now. And I think even as, as late as, last night, some companies were announcing that they are expanding their capability, here in US. So we believe that with this site, which we have here today with, with the capacity and also by expanding it, we are in a very good, good place. We continue to identify operational efficiencies. And one of the things which I can mention under this category is that we have managed to keep, the cost of goods, almost flat, since 2021.

And, of course, you know, that it has been some significant inflation over the last, the last five years. I've talked about, spending more on R&D, adding more product into our pipeline. And, we have decided that we are not going to necessarily count ANDAs we are going to focus on value more than numbers.

And, and, I think that's, that's quite different from how most of the companies are doing this and how, how, both in the past and still today. So, so we have been installing a new technology into the site. You saw the nasal lines, you saw the Advair line, even though maybe the speed of that line was a little bit disappointing today. We talked about the respiratory expansion, and, so I don't really need to, go deeper into that, but both, both christen and but I will talk more about that.

And I think one of the things which I was asked about yesterday was the epinephrine nasal, which, we are, hopefully going to file now in the second quarter of, of this year. And maintaining the highest quality standards is, of course, something which was talked about in 21. And we will continue to, of course focus on that moving forward with that.

Tyson, I'm going to give it over to you.

Tyson Ardo: Thank you. And good morning. So even though Hafrun put quality last we usually like to start with quality here in Columbus. So obviously you've seen our beautiful facility. And we know that that is a differentiator for us, but it's really a differentiator for us because of this quality record that we have. And it's important to us for our base business is important to us in attracting new CMO partners.

So we're very proud of our quality culture that we built here. I know we mentioned on on our tour, but what you saw out there is what our facility looks like every day, right? It has to be because the FDA can show up at any time and be on the floor within 30 minutes. And so it's really important to us that we're always operating in this manner. And this slide really represents that. Right. So each of these bubbles here we call this the bubble slide represents a regulatory touchpoint that we've had over the last decade that really it goes back 20 years. But the slide gets pretty busy that way. So each of these was an inspection that we had without any critical findings.

Right. So a successful quality inspection, you can see a lot of FDA and DEA, which is domestic, obviously important to our success, but also we have international, regulatory agencies here because we do produce product in this facility for some of our CMO partners that are distributed in 80 countries across the world. So that's also important for us as we look for new partners, that that's a capability that we have.

I know we pointed out the the quality promise when we were on the tour. So, every employee signs that quality promise with some regularity. We refresh it every few years. But also this room is where we host our new employee orientation. And you can see over behind Brett, we have a small copy there because it's important not only our current employees, but our new employees understand what they're getting into. And so in every new employee orientation, we have them sign a copy of our quality promise so that they can also say that they were a part of this. So that's how we kind of maintain our quality culture that we have here. And just one more thing I'd like to point out here. So kind of this pink bubbles here, this these aren't inspections, but this is another touchpoint that we have with the FDA.

So we're very proud to serve as a training partner for them as they train new inspectors on being pharmaceutical inspectors. Right. So each of these represents a cohort that has come through our facility. We've showed them similar to what we showed you. Here's our technology. Here are the operating principles. Here's what a mature quality system looks like. And so they keep coming back for more. And that's something we're very proud of. So obviously, this is important to us. It's, it's, something that you saw today and I'm glad you could be here. So, Mike.

Mike Balog: Thanks. You bring me down with the tie Tyson, and, I guess that's the quality difference.

Tyson Ardo: I will say several of us discussed ties earlier. I'm the only one that came through. So.

Mike Balog: So I was happy when we kind of announced that we were going to do the tour first, because I think that makes my presentation a lot easier. What I hope to do is tie together a lot of the loose ends that we covered on the tour, etc. but this is an aerial view of our facility. And I think part of our quality, success is really driven by unbelievable infrastructure, that supports all of that. We do a lot of manufacturing. We do manufacturing well. I think that's a common theme across all of Hikma, all of the sites, etc.. So we're in this area here. If you recall from the tour we walked around the building, this is where the CMO expansion, you know, to the tune of, you know, almost 250 million between facility and equipment that we will be investing in that area.

This is the dedicated potent compound facility or isolator technology, that we talked about. I know we got to tour the GCS area. The two lines, are in that area in the facility. So that was about 160 million, in capital expansion. But we also spent a lot of time in the core of the facility, covering a lot of the solids and the liquids technologies and where we're differentiated, from others.

So let's get into the details of that a little bit. So I introduced this term a couple of times. Hopefully you guys picked up on it kind of the white tablet. So this these are well understood technologies in industry. These are the ones that are probably the most vulnerable relative to increased competition price erosion. Etc.. This category we do billions of tablets if you will. It's a lot of volume. It's lesser value. It's still good value. It helps us on the absorption. We still want to do a lot of that. And we currently do a lot of that to the tune of 3 to 4 billion. And that number is only going to get bigger over time. But we really make our hey is in the differentiated technology.

So billions in this area, tens of millions in this area. But the margins and the value and the number is way better, much fewer players. So a lot of the products in that space, you might have a dozen players more subject to go low cost center overseas. Typically, North American produced products, especially in the nasals and the respiratory and a handful of players or less the nasal. Specifically, we're the number one producer in sales and volume, and we talked about that. So I'll spend a little bit more time on that. Fluticasone specifically, that was first launched as a generic in 2006. So here we are 19 years later. There's only three players were greater than 50% of the market share. And we're as strong as we've ever been in that regard.

That's what really clued us into this space being an opportunity for growth, which is why we've got into the by dose, the unit dose. There's different nasal technologies, not just on the production side, but the lab equipment that you guys saw to really support, leveraging that to a limited number of players. Respiratory is kind of in the same category. The dry powder inhaler. There's still only, three generics producers on the GSK, I guess four if you count Prescott from the from the authorized generic, etc.. So we have a strong presence in that area. We've proven the ability to succeed in a very, very difficult technology space. It's much bigger than managing the API. The lactose and the technical consideration.

I know Chris will get a little bit into that relative to the next generation of products, but we've proven on the disc platform we can have success. We're very few people have. We want to kind of leverage that into some potential future growth with the Ellipta. So this has been a once again, a very small number of players growth area, the high containment, we actually have a decent amount of excess capacity in that facility. But that's another differentiated area, producing those potent compounds I had mentioned on the tour. Everolimus is a product. You have methotrexate, colchicine. There's some of our portfolio contributors in this. So once again, high volume, lesser value, lesser volume, high volume. But it all matters when we we kind of coach our employees if they want to be in one area or the other, it really it all matters. So it's all contributing to our total success.

To put some visuals to some of the products specifically on like the white tablet side of things. Dexamethasone was it was a nice little boon for us, during the Covid era when when Covid first hit, we were the 95% producer of that specific molecule. So we got a few good years of contribution, from that, a lot of competition. We've had multiple entrants since then. So once again, being a white tablet, the competition comes heavy and fierce. Buprenorphine naloxone. We're still the number one supplier of of this one. This is a key. And breaking the addiction, cycle. So that you never end up with an overdose type type event. So that's been a very strong product for us.

Very efficient in that operation. Furosemide was our highest volume product, a very common diuretic. At its peak, we were doing a billion tablets of that per year. Volumes are going down is we we see more and more competition. But all of that volume contributes to our overhead absorption, making our entire portfolio better. And then as we talked about some of the more differentiated products, this is the DPI respiratory. We do three strengths of that product. We have a good, good presence in that market. We have a second line that we're bringing on for redundancy to make sure that we are able to keep ourselves, well positioned in that market.

Kloxxado, this is the venture into the unit dose. We're getting a lot of, hits on this in the contract manufacture thing.

So besides supporting our own pipeline, which we'll talk about, we actually have a lot of additional capacity to help others out. Same thing. Limited number of players that are that are doing that. We've proven to have a great expertise in the, in the unit, those technology.

And then fluticasone personally my my favorite this this product is, blazed the trail for a lot of different successes.

That specific product, we produce on the side, but we also have an OTC partner. So we've diverse diversified within that. So that'll give you some, I guess, visuals to to stick in your head. We also do distribution in Columbus. A couple of nuggets that I'll add on to what Hafrun said about the Columbus area. Columbus is very centric in the, in the U.S. so you're within one drive, one day drive of 60% of the population. But independently, if you were if this facility wasn't here, if you were going to want to have the most desirable location to have a generic distribution center, Columbus would make total sense because 80 to 85% of what we sell go to three primary buyers. Two of them are in Columbus between Cencor and Cardinal Health. Those two facilities are two miles away from our distribution center.

So two thirds of the players right here, the other one is in Olive Branch, Mississippi. So it makes total sense. We stood up this operation when the site was acquired. So it was a purpose built in 2016. And I believe that we do this very cost efficient relative to, some of our, our peer group.

I'm going to do one minor correction on what you said. You said second largest employer. We're the second largest manufacturing employer in the area. So we have a large Honda plant in the area. But Honda is the only one, from a manufacturing side that has a larger, workforce population. All of the controlled substances we do distribute out of this campus, none of that goes to that location.

Anything else to mention on distribution? I think that's probably a good, good summary. And then, growing CMO business, we have a very, very large facility. Volumes kind of come and go depending on what the market is doing. So we are leveraging more and more of this as an opportunity to better utilize our facility. So we're expecting a CMO revenue to be north of 20%. We believe the volume is probably going to be a larger number than that, but we see this as a key part of our success formula beyond the differentiation between, white tablets and the different technologies. This is a key part of our success. A couple of the disclosed customers. So Boehringer Ingelheim, when we acquired the site from them, that one of their products, we produced that relationship actually, when the deal was done was supposed to end in 2021, but we've continued to produce for them or one of their major, suppliers.

We've taken it from their previous molecule Trajenta to Jardiance. So if you guys see those commercials, you know, we have, some of that produced here in this facility. We've extended that relationship. Perrigo is our partner on the fluticasone OTC side of things. And then we have seven other customers that we will leave unnamed.

Those are, I think, relatively out in the public. But, a key part of our success is to keep the utilization high. It makes all of our operations better and more efficient.

Chris Edlin: Thanks, Mike. So, because of the intimate and synergistic relationship between R&D, business development and portfolio, and are you going to do a bit of a double act over the next, 5 or 6 slides or so? So I'm going to take you through the footprint and some of our growth plans for R&D of the next few years. So, if you look at this slide, we’re going to go around clockwise from the bottom left.

You've been here. You've seen the site. So I'm not going to cover that. Mike talked about it I haven't talked about it. You've seen it but we have about 100 scientists here. In addition to the QC scientists who are moving forward, the products in development and also supporting the lifecycle of currently approved products to we also located with Regulatory affairs colleagues and people from business development. And as you've probably seen as you've walked around, we're focused on complex products because we believe it's going to help us maintain and create differentiation going forward. Moving further right. We have corporate offices in new Jersey. So, Hafrun sits there, Kristy sits there, our segment lead. We also have some more science and BD and pipeline people there as well moving further around.

So I want to talk a little bit about Zagreb in Croatia. So as part of the acquisition that Hikma made of Xellia, there's a site and a number of excellent scientists there that are now working on injectable programs and Ragheb and co, will talk about those this afternoon. But we saw that as a fantastic opportunity to leverage our capability in Croatia and build and expand the generics capability and capacity and a cost effective environment. So we've been highly impressed with the level of skills and people that we can access and the talent pool in the area, and we're building a team that at the moment, we've hired one person to be the leader of our organization. She comes of a wealth of experience 25 years working with Xellia and Teva in the country.

Our initial focus there, apologies for the typo. Is going to be on simple, solid products as we try and move us forward in a cost effective way. Moving further on this slide, we have capability that you've heard about over the last few hours or so in Jordan, and we co-develop a number of programs with our colleagues over there in two locations in Jordan and Biadar and in Sahab. The latter of those facilities, Sahab has got excellent, high potent capability, and we're looking to try and leverage that, capacity in Jordan as we move forward. A couple of other interesting points about, capability in Jordan. So Hikma has an API facility, Hikma Chemicals, we're working with those continue to make sure that we can vertically integrate some of our programs.

That's a relatively low volume, 5 to 10 kilo niche API producer. In addition, we have a 51% stake in a clinical research organization, IPSC, the International pharmaceutical research Center is prosecuted more than 4500 bioequivalence studies over the years, and it's FDA and EMA approved. So we use that as much as we can to make sure that we can, maximize agility and dynamism with our projects going forward.

So I'm going to pass off to Brett.

Brett Bukvic: Thank you very much. So I'm going to talk about how we decide what products we'd like to add to our portfolio. Obviously we have a phenomenal commercial portfolio that's on the market today. But one of the key processes within all of our businesses is deciding which products we want to target and how we will execute against those targets.

So on the left, we basically look at the universe of potential products we can go after and say based on commercial criteria, competitive dynamics, loss of exclusivity, expectations, barriers to entry. From a technical perspective with no constraints, what products would we ideally like to have? And then we whittle that list down to a manageable level and say with within this refine list between Chris's team and my team, from a BD perspective, how do we go after these products?

So that whole process involves bringing together all the subject matter experts from across the business from manufacturing, regulatory, R&D, IP, legal, commercial, really, everybody, OSHA, like everybody that's involved in that process, has their input into the business case, which is both, quantitative, obviously, but also, qualitative in terms of how we can actually do this, what we can do internally and what we can do, with a partner.

So throughout that business case generation process, we look at three main criteria, which are really, timing. Can we be in the first wave of entrants as a generic or a 505(b)2 do we have the technical capabilities internally to do everything we need to do or do we need a partner? And then three, if you look at the business case and it's highly risky and involves a lot of, upfront investment, whether it's CapEx or OpEx, do we want to share that risk and reward with the partner based on those criteria?

If all three of those are checked, we will always choose to go. Almost always choose to go internal, right? If we if we don't need a partner for that, we have full control over the execution of the program, and we have full control, and the ability to realize the, the economics once, once commercial. And then in that bucket on top, we obviously decide what makes the most sense to, to put that product in Columbus, Amman or Zagreb and then utilize the chemicals and IPRC to do that as efficiently as we can.

If one or more than one of those boxes is not checked, we'll look to partner, to execute against those products we've chosen. So there's many different ways we can do that, which I'm sure you all are very familiar with, but just a few examples of which products, fall into those buckets. If timing is an issue, and we can't be there by starting a product from scratch internally, we'll look to a partner.

We recently announced a deal with a company called Novugen Pharmaceuticals, who had a first to file product. It's called trametinib. It's. It was a race to file, as we call it. The n c minus one date had passed. So the first generic to file on that product could obtain 180 days of exclusivity. They did that successfully. And and one of the attractive reasons, it makes my job easy to have a commercial team, like Kristy and her team to kind of, articulate our abilities to potential partners is we have such strong relationships with our customers and have such a good infrastructure to be able to maximize the value of, of our own products and partner products. It makes us a really great front end for deals like that. The second one is if we need a partner for technical capabilities, sometimes it's not something we can ultimately do internally, and we'll use them on an ongoing basis. But ideally, we'll be able to leverage their technology to bring some of that capability in-house. A good example of that is, generic Advair, as we've talked about a bunch. And on a future slide, I'll talk about some of the next generation, respiratory platforms that we're actively pursuing and looking to partners to help us, address those areas as well.

And lastly, from a cost and risk perspective, the Emergent deal was announced, back in January. That's one where we have a 505(b)2 that we see a lot of value in. There's a lot of synergy between our manufacturing capabilities and their commercial infrastructure, where we did a deal that I think is mutually beneficial for both companies as well as patients to be able to get that product in more, more hands. So many more examples. But those are three, I think, pretty salient ones that articulate how we, really funnel products internally and externally. And I'll be back in one slide.

Chris Edlin: So, what does this mean? What does this, how does this define our portfolio and our pipeline? So I'm just going to take you briefly through the overview of the product split and the development phase. That we have currently. So I think, when you look at it by phase, clearly

we've got a reasonable give or take, 50, 50 split between products in development and products that are either filed or approved or tentatively approved.

We manage this process robustly. So we have quantitative, risk based models that we use to prioritize, projects and resources. So we do that in a dynamic way to make sure that we're optimizing the resource that we have. When we look up products by dosage form back in 2021, we made a commitment, for example, to increase the emphasis on respiratory programs. Back then, respiratory and nasal programs constituted 8% of the split of products. Now we've taken that to 20%. The majority of programs are still represented by biosolids, but actually the 68% of activity that we have in solid represents the majority of LOEs over the mid to near term. So we think we pretty well balanced there.

We've made a significant increase in paragraph four filings. Paragraph four filings, as I'm sure you all aware, require a bit more effort from an R&D perspective to either find, non infringing positions or more support from our legal colleagues as we, navigate some challenges as we move forward with those in development. Currently, we have 14 programs in paragraph four, progression status.

So I'm going to pass back to Brett.

Brett Bukvic: Thank you. So to provide a little bit more granularity on, on the rightmost, pie chart here, as Chris mentioned, we kind of replicated this slide from the 2021 presentation. We had a similar view, but, we'd like to provide you all in the market with as much insight as we possibly can with our disclosed filings.

So what you see here is a list of of all the P IVs that have been filed in our in our public, on the left, you can see, all the filings that are first to file. So we're either the sole first filer or in a shared first file position on the right, our follow on P IVs, where we're not in that first group but still have the ability to, ideally launch on day one, 81. This list was only 8 or 9 products last time. And I will say this. This only includes what what's been filed. So there are obviously products in development that have not been filed. And this will keep keep growing and some will fall off as they launch. But the main takeaway here is we're really trying to balance what products we choose between kind of easier, quicker, maybe smaller wins where there are no, legal implications. And we can realize that sales earlier and typically higher up side products, many of which are on this list, where you don't necessarily have as quick of a path to market. But you do have, the ability to have that exclusivity, in many cases and realize a higher sales potential. So many, many of the launch dates aren't disclosed here because we are unable to.

But I will point you to the fact that, one, there's a mix of good, internal programs as well as programs that we've, done with partners so that you can see the legend on the bottom right. There's five BD deals, and then the rest are all internal, where we'll manufacture here. And those will touch different areas of the site, whether that's solid orals in most cases or there's two nasal sprays on here to just to bring this to life a little bit more than rather than just giving you a long list of products.

I'll point to, esketamine, which is this, this one right here. This is a bi dose nasal spray that, the RLD is a product called Spravato that J and J markets for depression. We admittedly chose this product a little late, and the team collectively did a phenomenal job of developing a customized device with our device supplier doing all the other R&D work associated with that, and then filing on the NCE minus one date. And that total time frame was 16 months from the decision to to go to hitting that date, which I think speaks volumes about our ability to coordinate across, different functions and really hit those key dates to put us in a position to launch in the first wave. Another one, kind of on the opposite end of the spectrum a bit is fidaxomicin.

This is a more recent, new project start that we executed. There were a couple of filers before us, but this was one where we thought, we can pick this quickly, file it quickly, and then be in a position to settle with the innovator in a reasonable time frame to to give us a nearer term launch. So an example of a P IV that you're not looking at a launch date that's, you know, seven, eight, nine, nine years out.

So I think that provides a little bit more color to the, the pie charts.

Switching gears a bit to the middle pie chart from the last slide, when Chris talked about the respiratory products that there were, we're looking at these. So I'll go one by one. But the three platforms you see here really represent the three main devices that are on the market today. On the left you have the Soft Mist inhaler, which is Respimat is the RLT that that is on the market today. And then the middle you have the Ellipta platform, which is the, the once daily version, from GSK kind of the lifecycle management progression from the Diskus to, to and then on the right, there's I don't know if you can see the bottom, but LGWP pDMI's stand for lower global warming potential pressurized metered dose inhalers. So I'll get into that in a second. Then on the left, we, we have a partnership with a company called Invox who, have a phenomenal team of individuals who have spent most of their careers in device design and development. We've been working with them for a couple of years now on, generic versions of, three products that are, that are in the same device.

All of these are large opportunities, as you can see here, multiple billions of dollars in the US alone. A highly complex device. And we're, really excited about the progress that we've made with Invox and look forward to to filing that in 26. On the Ellipta front, we have a device, identified. And we're currently kind of validating whether that is our ideal selection to really select as what we want to go after from a for a long term, play with the, with the partner.

And that will, that's something that will probably be announced in the, in the coming, coming months. But nothing today. On the right, yhis is a, I don't know how familiar everybody is with this, but there's kind of a we're in the early stages of, of the market, of PMDs switching from the current propellants to a new generation of propellants that have much lower impact on the environment.

We think this is a way to partner with, a key player in the space to to be able to leverage their legacy in the area, as well as our internal, advice that we can provide them as far as development and manufacturing in the respiratory space to be a first mover as that market shifts to the new propellants.

So that's another one we're, we're very excited about and, look to announce in the coming, coming months as well. The last thing I'll mention is all of these, as you can imagine, are very expensive to develop. So we try to balance what will ultimately hit our opex. From an R&D perspective, as well as shifting some of that risk between us and the partner in the form of milestone based, success based payments, to be able to manage all of these investments, which, I'm really excited about.

But between these products, some of the complex products that that Chris has mentioned and Will mentioned, and the P4 is and the team that we have, I've never been in my time here, as excited as I am about what we have coming in the pipeline and what we have, to, to grow at the top and bottom line going forward.

Chris Edlin: Thanks, Brett. Over the last R&D slide. So actually on the LGWP piece, the first approval happened this week. So I'm sure you saw that AstraZeneca had a triple combination approved in Europe. So this space is moving and evolving. So I just want to cover some of the new technologies again. Back in 2021, we made commitments to do more, to be more complex, to continue the differentiation.

So we invested in, liquid filled, capsules, soft gel capsules. In fact, we made a submission early on this year using the soft gel technology. Hot melt extrusion. Again at the end of last year, we made a submission of it with the product using that technology. So that was developed actually with our colleagues in Jordan. So hot melt extrusion followed by cryo milling. So again, increasing the complexity, and again, to make sure that we can move all of that forward, we've made sure that we've recruited key talent to make sure that we're able to deliver against these technologies. I'm just going to call out, one particular example in the, complex area. So generic, Entereg (alvinopan). So we selected that, and we started development in 2022. We submitted it in 2023. We launched it in 2024. And now we have a 24% market share in a four player market. So I think that's a great example of how we've been agile and use new technologies to drive forward programs.

On the right hand side. You saw today as you walked around our capability in nasal sprays and aspirations to grow in that area too, we're building on on a really solid, commercial foundation. We have a number of programs that we've developed and submitted internally, but I just wanted to call one out. So epinephrine, a single dose nasal product.

We're really excited by this program. We feel that there's really solid data that differentiates that from other products that are out in the market. Unfortunately, we can't share specifics at the moment, but watch this space. We're certainly super excited about it. And we have a number of other 505(b)2 applications falling down the track, again, utilizing the in-house R&D capability with the view to manufacturing and leveraging our solid foundations in, commercial manufacturing.

So with that, I'm going to pass over to Kristy.

Kristy Ronco: Thanks, Chris. So I will spend, the next couple of minutes just taking you through some of our, commercial efforts, at understanding a little bit more about the markets we compete in. I get the privilege of being externally facing, and share all of the work that this team does. And, and really be part of, be a proud part of the Hikma team or Hikma Rx team.

And so first things first, I really wanted to just talk about the market landscape. Right? So it is a bit challenging. It's a bit complex. Over time we've seen more vertical integration. And it does make things a little bit more complicated. Once you understand it and you understand the players and the partners, then you can simply break it down and be successful.

So what I provided here was, a visual just to show, one area of, of vertical integration and vertical alignment in the distribution channel. So starting with the, the manufacturer and the wholesaler, obviously you have the big three, which Cencora, Cardinal and McKesson, they roughly, support 90% or distribute 90% of the generic pharmaceuticals in the US market. And then within that channel you have various other entities, and types of entities. So you have, the, the pharmacies and the PSA O's. Right. So you have this pharmacy, the regular independent pharmacy and the specialty pharmacy, and then the PSA. So what they do is they provide services to those independents. Then you have the payers and the PBMs, and the payers and the PBMs are essentially what is crucial to bringing the product from the wholesaler through dispense adjudication and then to the consumer.

And then we have what's the patient access services. So those patient access services act as a hub. They support with prior authorization copay services. And they really are, providing this kind of end to end, vertical alignment and integration to ensure from, product procurement through dispense. They have management, within that channel, other vertical integration.

You know, if you look at CVS health, CVS, health has, integration through the PBM. And they also roll up to a procurement arm called Red Oak Sourcing and Red Oak Sourcing also includes Cardinal. So together Red Oak procures on behalf of both entities. So we do see that vertical alignment throughout switching gears a bit to the regulatory and dynamic markets.

So I had the privilege of talking a bit about this last night. And every, every morning we wake up to new news, and new regulatory and, and geopolitical changes. We, thank President Trump for keeping us on our toes. But today we feel that we are well positioned to be able to compete again in these, in this changing landscape.

DSCSA, which is the Drug Supply Chain Security Act, this was a, heavy lift and something that was challenging for the pharmaceutical market. And I'm happy to say that we were in the forefront in terms of being, ready early on. We partnered with, the big three that you see there at the top in terms of testing, we have a consistent 99%, 100% service level scorecard for all of our U.S products that are distributed.

And this, we believe, could open up opportunities, whereas some of the smaller suppliers may not be, ready. In terms of leveraging other programs, we did see the benefit of IRA. So the Inflation Reduction Act, which is intended to, manage the, mostly the brand, pricing once we saw the top ten products come out, and we saw the impact of IRA, we were able to benefit from accelerated brand to generic conversion on products like generic Advair.

And same with the 340 B program. Right. So that has been able that reform has given us visibility. And we're able to manage from a revenue leakage standpoint, ensuring proper, rebating and visibility to those, hospitals that are eligible. Moving on, in terms of our reputation, I will tell you that, I think Hafrun you alluded to our scorecard?

Yes. We are consistently, one of the most highly rated, generic suppliers from our customers. Their opinion matters the most. And our strong, quality scorecard, and record, definitely, supports that. We are a consistent supplier. If you have if a customer gives us an award, they can sleep comfortably at night knowing we will supply.

So in terms of our portfolio, I know, Chris and and, Brett did a great job talking about pipeline. This is kind of a, a view of our current portfolio and the products that we compete in today. So overall, we compete in, a little bit more than 110 active molecules on the market today, over 330 individual NDCs.

And if you were to take that and break that up, you would high level say about a third falls in the oral solid, another third in the solutions and suspensions. And then about another third in the nasals and respiratory and inhalants, and a small, small bit in other. But really if you were to just kind of high level break it in thirds, that's how we would, break down that portfolio.

Once you start taking a deeper dive into the markets we compete in, how many competitors are out there? What's the environment? The majority of the products that we're in today, over time, have grown to be at a 6 to 9 player market. What's important to note, though, is in the markets that we compete in, they might get competitive over time. We are in the first or second market share position in nearly 60% of our portfolio. And that speaks volumes to the team and to our partnerships. We work with our, our, customers in terms of long term agreements. So we're not always looking for that consistent turnover. We're not only, competing on price, but we're competing on consistency and value, over time quality.

And with those attributes, we're able to secure longer term awards, which is great. It gives them, a surety of supply, and it gives us consistency in our planning and our forecasting and management, managing the plant appropriately. Taking a deeper dive into our our larger products, I knew Mike wouldn't be able to get through his presentation without stealing some of my thunder.

So, but I will start with sodium oxybate. So I really wanted to take a moment to just take you through some of our key products. What you know what? I see them as pillars to our success. And, really is a a nice, view into products that we have organically, formulated, produce here.

And others that are through, inorganic growth, whether it's a partner product, or an authorized generic. So first things here is, is sodium oxybate. Sodium oxybate is the generic, Xyrem. We have the authorized generic of the Jazz product. This was, launched, a few years ago, and we have successfully, been able to convert patients, to our authorized generic product.

This market, is a it's a niche market, right? It's not a significantly, high in terms of, of active patients, but it is growing. It is growing at rates, that we, you know, early on didn't necessarily

anticipate. And I think a lot of that is because now there's more cost effective, therapies out there.

And, we are we are happy to say that we expect there to be, a 10% global CAGR, for growth here. In this market, Jazz has, and runs a very complex REMS program that, as the authorized generic can excuse me, we are part of, this REMS program requires a single specialty pharmacy distribution and single, specialty pharmacy dispense. And so we work within that channel today. And like I said, we are very happy with our progress, in terms of, conversion to our molecule, or our label, for this product.

Moving forward, we will also look at, potentially bringing our own ANDA to the market, which was, received approval in 2017. That was contingent on a successful REMS. Or we will look at continuing our existing, AG, products, commercializing that product. And we will make the right decision. That's right for us. At that time

Switching gears a bit to, the fluticasone salmeterol. So that is the generic Advair. And again, a complex product, challenging market, but a market that did successfully convert, to, 99% generic utilization, once the IRA hit. So that January 2024, IRA came into play. And, 50% of the brands, retained market convert it over over time, Hikma became the largest market share holder for the fluticasone salmeterol.

As of March, we were at 34%. And I believe we will continue that trajectory we've made, vast investments to ensure redundancy, to protect the supply chain of our partners, and then to allow for additional growth in this market.

Fluticasone OTC. And Rx. As Mike said, we do have a partnership on the OTC with Perrigo. And in on in the we are seeing growth there as well. Historically we've seen mid-teens and double digit growth. We expect that trend to, to continue. And due to the efforts of Mike and team, we're able to support that, growth. And, we look forward to that. Finally, in the respiratory space, we have, the albuterol, the albuterol market is growing as well.

As a matter of fact, if you look at all three of these products, and that respiratory space continues to grow, and that's why we we, welcomed Chris. Definitely to the team as we, as we continue that focus in that niche market. Albuterol, we compete in this kind of generic space, which is basically basically ProAir, Ventolin and Proventil.

So those are your three, inhalers, that exist today in the, albuterol space and over time, the Proventil, which is the product that we currently commercialize, has grown. So from 21 to 24, we have gained ten points in market share. And we have successfully converted much of that market, to our product. And we will continue to do so.

Finally, one of the things I wanted to point out, we talked about this a little bit last night at dinner was synergies. Right? So we have the benefit of having a lot of expertise within our total organization. And we try to work collaboratively so that we don't duplicate efforts. We don't work in silos.

We manage costs, but then also we have that in-house expertise. So, I have colleagues that are in the European market, and those that are in more in the institutional market, which you'll have

the pleasure of meeting later. And so we go to each other to make sure that we can, best, support the customer and the commercial efforts.

So what I wanted to do was kind of illustrate. So liraglutide, was the generic Victoza. Hikma was the first approved ANDA to the market. And that is obviously a daily injection in the GLP-1 space. It is an injectable product which normally would be in the, commercialized from our institutional injectable team. But because it is a retail based product, we were able to collaborate and assist in making sure that that met its utmost, capabilities and, and market share. This we had the privilege of launching, on or around Christmas Eve. And so, Joel and team can pay me back later. But we were successful at increasing our market share, quickly. So within the first three months of launch, we we successfully grew this market. And we're pretty happy with our, our market presence. That you see over here in the first quarter of, of February 25th.

On the flip side, Indomethacin suppository was a product that, we had a brought to market in terms of Hikma Rx, and we were able to then go to our colleagues on the injectable side, and, and get their institutional knowledge, and partner with them and their relationship in that GPO space to ensure a successful launch and a go to market strategy focusing on more of that institutional, demand.

So if you look at everything holistically, we are serving our customers, end to end. And we believe we have great success doing so. So with that, turn it back to Hafrun.

Hafrun Fridriksdottir: Thank you Kristy.

So I hope that you are as excited about our business as we are. And, you have seen a lot of capabilities and a lot of, improvement, a lot of plans for the next, the next few years from from the team. As you probably know, we reached the revenue of $1 billion last year. Of course, we we are planning to to grow the topline, but we are also planning to grow the the bottom line, moving forward, even without mentioning any, any percents.

But that's, that's something which we which we are well positioned to do. You saw the, the the growth in R&D. You saw the growth in, in the CMO business. And you also heard about how much we are we are spending on our CapEx. So so of course we want to see a huge return on investment of all those, all those, money which we are spending both in R&D and, and CapEx.

So I think with that, I'm going to thank you for, for for your time. And, we will be happy to answer your questions later, later today.

Injectables

Speakers:

Dr Bill Larkins	*President, Injectables*
Joel Rosenstack	*Chief Commercial Officer, US Injectables*
Nassim Rahmani	*AVP Commercial, Europe Injectables*
Natheer Masarweh	*SVP Operations, Injectables*
Ragheb Abu Rmaileh	*VP R&D, Injectables*

Bill Larkins: So I'm Bill Larkins, president of injectables, been with Hikma now for three years. I came to Hikma via the, acquisition of Custopharm. Took over the role of president of the division when Riad stepped into the CEO role in September of 2023. So I've been in the role now about 18 months. I'm a scientist by academic training, so I have a PhD in chemistry from right here in Columbus, Ohio with the Ohio State University. So, and then most of my career, the first half of it was in, various leadership roles in R&D for both branded biotech companies and also in generics. In the second half, I've been, leading injectables businesses, including the Bedford business, until it was acquired by Hikma back in 2014. So I had a couple of different stints with, with Hikma through the years. I'll let my team, introduce themselves as well.

Natheer Masarweh: So, I'm senior vice president of operations. I started in Jordan, in 1993. I've been with the company for 32 years, and I moved to Portugal in 2004, and I took several, positions in quality, technical, and, operations recently. When Bill took over from, the the division, I became the operations guy.

Ragheb Abu Rmaileh: HelloEveryone. My name is Ragheb. I'm, VP of R&D for injectables. Like Bill, I have a PhD in pharmaceutics. I've been with Hikma for 12 years. First two were in Jordan in corporate R&D. It was at that point. The last ten were in Bedford. I came, very soon after the, acquisition, that we made. Prior to Hikma, I had, a stint in AstraZeneca in the UK, working in, early development. Late stage development. Took up a few commercial assets. Really from early stages to, what what became commercial assets. Nice to meet you.

Joel Rosenstack: Hello, everyone. Joel Rosenstack, chief commercial officer for Hikma's, US injectables, business. I've been with the company for 11 years, just prior to the Bedford acquisition in 2014, and I've been in the industry for about 25 years with the majority of my experience on the injectable generic side. Nice to see everyone.

Nassim Rahmani: Hello, everyone. So I'm Nassim. I am, the AVP, Europe commercial. I joined Hikma nine years ago. A little bit less than nine years. My background is finance and circular economy. And prior to Hikma I worked in, consulting for pharma business and heavy industry.

Bill Larkins: Thank you. So I'm just going to spend a couple of minutes just kind of framing out what you're going to hear from the rest of the team today. I'll talk a little bit about the injectables business. What's unique about it. And then, my team will take it from there. So the injectables business is unique and, in a couple of ways.

So one, it's the only multi-regional business we have within Hikma. So we have a presence in North America, Europe and in the MENA. We're the biggest unit within Hikma globally. So we have, as you can see here in 2024, we were 42% of the revenue for the for the group. And 56% of the operating income for the group. In total. Across the last five years, we've had really strong growth in this business unit. And we'll talk today about a lot of the reasons why, with respect to our manufacturing capabilities, our R&D capabilities, etc.. But we've had a top line growth, CAGR of 8% over the last five years. And, 7% on, EBIT.

We're top three in the US in total volume of injectables and top five overall in revenue and injectables in the US market. We've got a huge portfolio in the US that you'll hear more about here in a little bit. We have more than 170 products, that we sell in the US, and we're growing quite rapidly both in MENA and in Europe.

And just to kind of frame out a little bit here, what you're going to hear from the team today. So we're, you know, we're striving on a couple of things. So to be number two in the US overall that's our aspiration top five in Europe and continue to have our market leading presence in the MENA. So from a pipeline perspective, we have three centers of excellence, that we have various types of technologies and Ragheb's going to speak more about it in a minute, but we have, an R&D center in Bedford, Ohio, which is a couple hours up the road. Some of you, some of you will see the Bedford site tomorrow. We have the newly acquired site in, Croatia that's doing a lot of our ready to use products. And then we also have an R&D center in Jordan as well, we're really focusing in. And part of our strategy is becoming a leader in ease of use products for the hospitals and patients. And so there's two elements of this that we're really focusing in on. One of those is ease of use for health care provider. So it's really working on things that, take out steps for physicians, nurses, hospital, hospital staff.

So that's ready to use I.V. bags, prefilled syringes, and then also ease of use for the end patients as well. So these are looking at long acting injections for better compliance for patients. Ease of use through auto injectors and other types of delivery technologies. And then we're also looking all the time at how do we upgrade our pipeline, outside of what we do just traditionally in our own R&D capabilities.

And so we look at partnerships where people have unique skills that we don't have and, or areas that we choose to, not invest in internally in our company. And so we'll talk more about that as we go through the day. Manufacturing is a is another one. It's it's really probably one of the the biggest competitive advantages that we have. We run really efficient factories. We're

continually upgrading factories and expanding the capacity in the factories. So a couple examples of that. Last year we did, new high speed line in Cherry Hill and new high speed line in Portugal. We have another high speed line that's going to go into Cherry Hill next year as well. We're expanding significantly, expanding our lyo capacity.

So we have this happening in two locations, both in Portugal. We're endeavoring to to expand significantly, and then also in the Bedford site that some of you will see tomorrow. We're doing a sizable expansion of lyo capacity there as well. The Bedford facility also has another unique thing with it. It has, aseptic bags. So we've had some products in development that we were looking for an outside CMO home for. But it's really difficult to find CMO, those that have the capacity to do aseptic bags at the scale that we needed to do it. So this, acquisition of the Xellia business was really good for us. So it it gave us the ability to find a home for the products that we already had in development. And now we've really energized what we're doing in this space to put significantly more products into development in this ease of use space.

And then we're also looking at, expanding regionally as well. So we have new plants that are, going to come online into this year, early next year, both in Morocco and Algeria. And we're now talking about breaking ground in, a new plant in Saudi as well. And then on the commercial front, there's a few things here.

So in our U.S. business, we've segmented into three different, segments recently. So we have our traditional base business, which is the traditional business that you that you all know well, which is our base injectables business. We just recently split off our differentiated products into a specialty division. So in that division we'll be selling our US biosimilars. Our non-opioid Pain branded product will be sold through this division. Vanco ready to use is sold in this division. And then all the products that we have going forward that require some type of detailing around features and benefits of, you know, what, what are the benefits of these types of products will run through this specialty division. And then we have our 503B compounding business.

Each one of these divisions has some specific dedicated resources to them that are focused primarily on that, on on that particular segment of the business. But then there's also really strong collaboration across, the injectables business unit with Joel's team. He has really deep relationships with a lot of the customers. His, sales force that's out on the field has great relationships as well. And so we leverage that across all parts of the business. And then I'd be remiss if I didn't also speak about Kristy. So Kristy and her team really help us out as well. On on right now and in our preparing for launching of our biosimilars. And as she mentioned, the case study on liraglutide as well. So we appreciate all of the help and support that you guys give us as well.

In EU, we're expanding really in a number of ways. We're expanding, really regionally. So expanding into additional countries that we're participating in, we're expanding within those countries with respect to more products, being introduced into those markets. And then we're also starting to now do some what we're calling purpose built R&D. So products that are specifically needed in Europe that we're going to develop for the European market. And then also in MENA, as I mentioned, we have a market leading position in MENA. Now, we have a lot of boots on the ground with respect to the ability to detail products. So we're continuing to

leverage that to move into more specialized products. So more diagnostic types of products, more, you know, kind of overall managing health in, in the MENA region. And so we're continuing to focus on that as well. And we're not going to talk so much about that today. But, Joel and this team will speak in detail about the US and the EU businesses. And with that I will, pass it to, Ragheb.

Ragheb Abu Rmaileh: Thank you. I thought Bill was going to cover everything I had on the slides, but, thankfully, he left me a few a few things to talk about. I think, similar to what Chris showed you earlier. We do have, three R&D centers of excellence within within Hikma. And I'm here representing, a number of very talented individuals across these, these different sites.

So I'm not taking credit for what they do. I'm just talking on their behalf here. I'll start with, with Zagreb. That's a recently acquired, site from Xellia, based, obviously Zagreb, Croatia, where we acquired a number of, the services of a number of very talented individuals. Just to flag, something that's very important. This is where the first and only ready to use vancomycin room temperature product, was, was developed. And we're very proud to, internalize that capability. And also obviously Joel will be very happy and the commercial team to sell the product, in that site, we, we do intend to leverage what we have been doing at the site, but also re-energize that pipeline with with more products ready to use, products, as Bill alluded to, these are, products where we take out, a preparation step, something like vancomycin.

Joel, which were very, kind of salient, presentation in his presentation graph earlier, later on. Sorry about how important it is to get access to the patient very quickly. So saving the steps is really important. There's also a different, category of ready to use products, or ease of use products for, for our, end users, where you take out the product from the fridge and we have a very good depth of mouse and room temperature product that we did also acquired with Xellia, I mean, in hospital pharmacies, this, this footprint is very minimal. So you really want to make sure that, you satisfy the customer and make sure that you get them the products that they, that they need. As Bill alluded to earlier as well, Zagreb is where we're going to do a lot of our EU R&D to, to boost the portfolio in Europe, which is which is very important.

Again, purpose, developed products in Europe to talk to the market needs. They are very important to, to be able to grow in the future. In, in Bedford, we have a focus group on a few technologies that we decided to, to kind of internalize. They're just based on skill set and capability is, along, drug device combination products depots and some of the complex APIs, which I'll talk about more in a little bit.

Jordan will continue to support our conventional platforms. Just from a, skill set and cost standpoint. And they are focused on the MENA R&D, which, again, like what we're doing for Europe. We really want to have a lot to focus on, on growing the pipeline. MENA. What's important to this path here? You know, when we talk about, maintaining and growing skill sets, within R&D, to support the development, medical, clinical, non-clinical expertise are really facilitate, you know, would facilitate the development of some of these, ready to use, ready to administer products which are very important, complex characterizations as we go into peptides and more advanced molecules are very important to, to internalize, gives us, cost control and

quality control over what we do, extractable, leachable nitrosamines, and drug device combination. Expertise is very important just in a, in a very, rapidly evolving, FDA and regulatory environments across the world, having these skill sets internally is very important.

More critically as well, we, we look at synergies all the time and, obviously with Chris's team, with the team in MENA, we really look at, you know, what skill sets we can or leverage and all, synergize. Obviously it gives us, again, more, more cost control and, in R&D and it gives us, a lot of quality control and an ability to respond to, deficiencies and questions from FDA.

If they want something, they want it. Now, we have there can be a capability to turn it around very quickly. Across the group, we do have, a lot of work that we do externally. We have good select, strategic partners as we work with, so just making sure that we leverage what's outside in the right way with the right partner, but also leverage what we have inside in certain co-development opportunities is important.

Moving on. And we'll see more detail as we go along. There are four strategic pillars that we have in R&D. And, and Injectables. The first is obviously we, we really want to continue to, to broaden the, the portfolio that we have, you know, to be able to cater for more, more product, from more product needs across all three, the, all three, regions that we work with, we also want to make, sure that we get, you know, more focus around the ready to use, ready to administer pipeline because that is something that is very important for us for the ease of use, again, leveraging on what we, what we acquired from Xellia, the skill set, and continue to build, to build on that and, you know, we currently have about 20 products in that category in development, in different stages, including ten products that are in aseptic filling, leveraging the, the newly acquired capability.

And, some of you will see that tomorrow in Bedford, but, just just finding that, capability to manufacture aseptic product is, is very limited. And I think, gives us, a lot of, in a firepower in addition, of course, to our existing prefilled syringe capability of Cherry Hill, which, which, which also is very important.

As I said earlier, we do have, you know, we serve all markets, so we want to expand our ex-U.S. pipeline. And we do that in a couple of ways. One is we take what, what is approved in one territory and we leverage it into different territories, different regions. And that gives us obviously, more, more, more scale for production when this comes to the market, but also it gives us the speed because we have the methods developed. We have all the, you know, how, so leveraging that and it gives us again that, that, that speed and and ability to execute. But we also, you know, through Jordan, through Zagreb, we will increase our Ex-U.S. pipeline. And we're going to we continue to add more products in that space. We, we like all the other companies.

I mean, the strategies are pretty similar. We want to get into more differentiated products. We do that, kind of based on evaluation of risk experience, expertise and cost sharing, which is not, far from what, what Brett said earlier in Hikma Rx. So we want to make sure that we get the right partner. And then, for in-licensing, people, we can work with people who kind of share the same philosophy about getting good products out.

But we also, you know, leverage what we have internally, to make sure that these are good products executed, well executed products. These are a few key areas that we identified as areas that we want to work with to increase the differentiation of the product peptides oligos and biosimilars. We also want to go more in and expand more into long acting injectables, Depots drug device combination products. Again, you know, it all starts with good product selection. And then based on our risk appetite, our, our expertise, etc., we can we can then, we decide where we put that on. And we had, you know, recently as, I think as you heard a couple of times, we had, the approval of liraglutide is the first in our GLP-1 and, through a good partner.

But, you know, we did we did leverage a lot of our internal expertise to, to make that happen. This is more about evolution. So, you know, on the, on the left hand side of the, of this slide, I mean, we brought our broken down into current capabilities where we have, you know, conventional, you know, simple formulations, development, which is again, core, to what we do and will continue to, to do it as we expand our pipeline both in the US and, and ex-US.

This fits really with our manufacturing capability internally. It keeps the sites and the facilities busy and occupied. It supports our base hospital business and allows us to expand to other markets. And, you know, as we saw earlier, we have 170 products that, you know, a lot of which were introduced through the conventional path.

We have also been working in the last few years on more differentiated products, suspensions, prefilled syringes, innovative bags through, through our acquisitions and the 505(b)2. Again, this stuff on the on this side of the graph here, or the slide here is something that we will continue to work on and bolster as a core capability, but we also want to expand more into the area here on the right, which is where we add complexity. And I'll show you a few examples later on, what these products are. But, you know, on the long acting injectables, auto injectors and complex APIs are the ones that we've identified, obviously, as as our pipeline continues to grow and expand, we'll see greater spend, of R&D budget, you know, potentially exceeding 60% at some point in the future, allocated to, to these, to these type of products.

I just want to give you a flavor of, you know, when we talk about ready to use, long acting and complex molecules. What what we're talking about. So I talked about vancomycin, daptomycin as products that have been launched through our acquisition. But we also have a pipeline, very exciting pipeline of, ready to use products in anti-infective and cardiovascular in emergency care, which, again, going back to the initial point about making sure that we cut the steps, reduce the steps in making and also when we can convert the product from refrigerated to room temperature, that's, that's very important. Allows health care providers to get more access to, to the, the products for crash cart, administration, etc.. On the auto injector side, we have liraglutide, which I mentioned, but we also have, some products in development now, in that, oil and hormonal, space. Suspensions, coming to this side here, suspensions.

We've, we've had a couple of, you know, in the last couple years, we've had a few approvals and suspensions. Some of these are pretty old, but, there's still barriers to entry from a development and manufacturing standpoint. So we see we see these as core going forward. We're also getting into adjacencies around the suspensions. So it's a new technologies new technologies that we implement.

There's you know, good market, good market potential. Because of LOEs, because of IP. These will be products to materialize out into the 30s. We also through partnerships have introduced, you know, microspheres, polymeric depots. The, the some are file, some are in development. Unfortunately, I can't really share a lot the names of the molecules. But, some exciting, you know, work is ongoing now with, to get some of these products out. Hopefully, like I said, in the 2030s, on the complex molecule side, biosimilars, I mean, we talked about these: ustekinemab and denosumab are two that have been announced, and filed with the FDA under, active review at the moment, on the peptides or complex peptides, we have one file through a good partner that we're going through the motion with FDA and oligonucleotides, again, this is another key area for the, both the innovator and the generic industry. And, we're, we're talking to different partners. We've identified a few partners for these that we, we plan to progress with.

So overall, I mean, you know, again, just to recap on this point, we appreciate the criticality of making sure that we have or we maintain our core competencies. But also, you know, expand our capabilities to make sure that we continue to, feed our pipeline with products that will have complexity and barrier to entry in the future. Thank you. Handing over to Natheer.

Natheer Masarweh: So before I just jump into my, a couple of slides, I want to just reflect on what Bill mentioned. And rather like over the years, we, we grew we've been growing in, 8% CAGR and we wanted to continue growing. We want to expand our markets, whether in MENA and Europe. And Ragheb mentioned that he wants to add also new technology in order to fuel our from, growth in the future, in the future.

So this needs to have an operation firepower to fuel this growth. And to do so, we need to have really, invest in operations and operations. What? I mean, it's not just only manufacturing operations. We have quality operations, we have technical operations, and we have also regulatory. So historically, under Riad’s leadership. And now Bill is building on it, and operations, we, we operate in, being cost effective, efficient, agile and able to, react to market demand.

So this takes me to our manufacturing footprint. So our manufacturing footprint did not come by surprise. It is by design. Based on the strategy that we have built on it. So when we started, we started in Jordan in a small sterile area. And the small sterile area, this is where we learned sterile manufacturing. Then we wanted to have a market presence in Europe. So we built Portugal and from Portugal we wanted to introduce new technologies, such as lyophilization. So we bought Italy as we wanted to be in oncology. We had Germany, then we wanted to expand on this capacity. So we expanded in Portugal and we created an efficient operation there. Then we wanted to be in the US. So we acquired Cherry Hill and we introduced there high being producing in the market for the market. And then we added new technologies. We added prefilled syringes there and also emulsion. Then we wanted to grow our portfolio. We in order to be agile, we bought Bedford Boehringer Ingelheim and we were able to to introduce the products as efficient.

Then we wanted to protect our market in the, in the MENA region. So we started with localization. We said Morocco and Algeria, and this is localization, which prevents market entry for, so we would produce in the market for the market and prevent competition. Then we saw an

an opportunity that in, in Saudi and we are investing in Saudi because that is this is a market is growing market.

So with all of that said, we are investing in the coming five years, we are investing around 500 million in order to, fuel this, this growth. And in there as, as I mentioned, here, Portugal and Cherry Hill are by far the biggest, manufacturing facilities that we have. So from technologies where, I mentioned about the technologies and how we are growing this, supporting the business and the growth.

So in Europe, Portugal is is the largest injectable facility that we have with a lot of technologies there. So in Portugal we do have, small liquid parenteral and terminally sterilized bags, a high containment facility, aseptic filling powder, which is the cephalosporins, the suspensions and, prefilled syringes. In the US, we started with Cherry Hill. We have the, we have bag filling, we have small parenteral, we have, emulsions and we have prefilled syringes. But now we wanted to add more technologies in the US. And this is where we are adding the aseptic filling and lyophilization. And this is by our new acquisition and, and from Bedford that you will see tomorrow.

In the MENA we're now started introducing the past two years. We started introducing, facilities. Building facilities and introducing technologies such as a lyophilization. And small and large, liquid parenteral and, and this is we started we have two facilities in Morocco, one Moroccan, one and Algeria. And we're also expanding and as has been mentioned in Saudi Arabia.

So with that said, we're adding capacity. And just to give you a bit about the capacity that we're adding into our facility facilities. So I will not talk too much about it, but like in the lyophilization, we're going to triple our, our current capacity we added the bags we're adding around double our capacity in aseptic filling. We don't have it, but we are adding this technology there with acquisition of, Xellia. So as an example, what we are like when we said we are producing in the market for the market, like in the US and in the introduction, we mentioned that we are third, in volumes just give you as a numbers, the market is around 1.5 billion. We're producing around 300 million units for the US market. And mainly if you see, it's distributed between 60% in the U.S with selling in the US and 40% with, bringing it, from Europe. So the question is you're adding all this capacity. Are you able to fill it? The answer is, yes. In the lyophilization, we do have some capacity constraints now that, we will be, filling this, by transferring, products into our, Bedford facility and the extra capacity also with Xellia. The beauty of Bedford facility that they are the same like for, like, transfer when we transfer it from Portugal to the US, which reduces the time. And one question in the tours about technical transfer and the cost. When we're doing like for like, it is much faster and cheaper and from a regulatory perspective it's easier to do it.

And from selling to the CMO our extra capacity. As we are not a CMO business. The CMO, when we are expanding, and this is strategically and historically this is what we do, we add more capacity up until we fill it up with our own products, we send this capacity, to CMO. And why does CMO come to us? Because the offering that we give is attractive to them. And it was proven during Covid with Gilead.

And now we also we do fill and finish for the US and for the rest of Europe, including Japan, with our partner, for the biosimilar, products. So the offering that we give is now with the with the extra capacity we can dedicate capacity to the partner, but also not just only in one region are having this capacity that we can we can offer in several regions.

The technical expertise are extremely important because when a client comes in, they need to make sure that we know our process well, that when we transfer the product, we transfer it in a timely manner and efficient. And in certain cases where the product is still under development, we support them in the pharmaceutical development and in the process optimization. And we've done that when we've proven that with our partner

Quality compliance is extremely important because the client wants to come in and make sure that their product is produced with high quality safety to the patient. And in any certain stage in the life cycle of the product, that you won't get any regulatory compliance issues.

And on top of that, we need to have really high service levels, which means that if we're going to give them a timeline that we service them. if there is a delivery schedule we give them if it's, full on time, in full, we do that. And also if there is any quality, issue that we support them in that. So having said that, that as an overall, you know, the operation itself, as I mentioned, is the, Riad usually mentions, that is the engine of the company. And this is how we are built being on efficiency, on cost, on agility and the ability to support the commercial and the business itself.

With this, I give it to Joel.

Joel Rosenstack: Thank you, Natheer. I have to say, I never get tired of hearing Natheer talk about spending money on additional capacity. And this is really the main reason, the top three competitors in the market on the injectable side account for 50% of the volume. So we obviously have customers that we need to take care of contractually, but just as important, if not more important, we need to step in. It's our responsibility for patients and for our customers to step in when a shortage arises. So that excess capacity, it's always very good to hear and, talk about. And it also helps us, as you know, we've been launching a significant number of products all the way back to 2016. We haven't launched less than ten products a year.

Many of those products are into shortage situations, which further strengthen a very strong relationship that we have with our customers, and in aggregate account for 43.5% of our current portfolio. What I like to see is the resilience of the products, over time, which really bodes well and speaks very highly of our product selection process. As we take a look here, I want to talk a little bit about our customers.

We not only really try to ensure we differentiate our product portfolio, so we also do the same thing with our customers as well. The group purchasing organizations or the GPOs are really the fastest way to enter a market and gain good market share. But we're also and they remain extremely important to us, but we also are focusing in on some of those larger IDNs that are starting to contract on their own.

And so we have relationships, on a more direct basis. We also are partnering with the 340 B and hospitals captured in the government section. And then as we have been talking about liraglutide and all of the support that we've been getting from the Rx team, we have a number of products that go into that space through the wholesalers, into the retailers products like testosterone and progesterone.

So really a nice broad portfolio of products that are also in many different channels throughout the industry. And then Bill mentioned that we have three focus areas from a commercial standpoint. The first one is the base business where we all know the 170 products that we sell to hospital, pharmacy and oncology clinics day in and day out. Really the primary focus is the great consistent supply that we have on a regular basis that customers really count on, and the low pricing and the sales team really their job, their role is to ensure maximum compliance.

We have the specialty team, which is fairly new, based in Chicago, inside sales. That really drives home the points of the differentiated products. Some of those products go through the PNT Committee, process in the hospitals, which could be quite lengthy once that team is successful getting the product on formulary, whether it's Combogesic, Vanco, premix, what have you, they will then hand it off to the base team who has great relationships and is in the field. Their job would be to ensure that the product gets purchased and pulled through. And then finally the 503B team. We do have some dedicated folks, and their responsibility is to really onboard the customer because our business on the base side, as well as mainly the specialty side, goes through the wholesalers. The 503B business, based on the regulations, needs to go directly to our customers, the end users.

So we need to, do credit reports on them and onboard those customers. They need to train on our e-commerce platform so that they could purchase the products. Day in and day out. And then once they're done with onboarding, it's again handing the baton over to the base team to make sure that they're getting good feedback from those accounts on what they would like to see, both in terms of new launches for our 503B business and in some cases, good ideas that we may decide to develop in our base business as well.

Okay, so, as Ragheb said earlier, we're really trying to get a little bit closer to the patient as well as the pharmacy. They providing them with ready to administer products. Of course, we have all of the products on the left covered. Your traditional vials, your a lyophilised powder. For those products that aren't stable in solution for a lengthy amount of time. And then in the US, to a smaller extent, ampoules. Now as we get closer to the patient and to the customer, we're launching a whole host of prefilled syringes, providing more value to pharmacy, taking steps out of their routine. Same thing with I.V. bags and then pens and auto injectors. Liraglutide again would be a really good example of that.

But the example that I'm really most excited about is our vancomycin premix product or Vanco ready, if you will, to product that we really were very intrigued about when we decided to acquire Xellia, last year. It is the first and only commercial commercially available, ready to infuse solution of vancomycin with no need to compound, dilute, activate or thaw.

So let me spend a minute on sepsis and why this is so important. As you can see here in this chart, it's a race against time. If you're a sepsis patient and you have a blood infection, that

infection is attacking your organs and it can be quite fatal. And in fact, you can see survival rates plummet as time goes on. Just within an hour or two of, being diagnosed. So prior to the Vanco premix being launched, there were a couple of things that a pharmacy can do. They can buy the product from a compounder. The unfortunate reality is that the products not stable for a very long time. So a lot of time that that product gets thrown out.

You can also, buy the frozen, bag. Now you need to make sure that that, is kept in a freezer could be quite expensive. You need as a patient, you're now waiting for this product to be thawed out and to be, placed by the patient's bedside. The other, thing that you can do and what many people have done is they buy the lyophilised vial, which, again, is a powder. They take the, diluent, which is also in a vial. You take a syringe. This one's a prefilled syringe. But just bear with me here and pretend that it's empty. You take the syringe, you draw the diluent from the vial, you push it into the lyophilized vial. You shake it, take the syringe again, pull it back, take a new syringe, put it into a bag.

And then you also need to check. Is this the right dose? Because it's weight based for your patient. So you need to make sure that there's not a medication error. You're doing all of this gowned up in a laminar flow hood with swabs and gloves and everything else. And then you get it up to the patient. It could take an hour or two hours and sometimes more.

So enter the vancomycin premix bag where we have seven different sizes and strengths to really cover the majority of patients that need it. So when I say this product is truly a lifesaver, it really is, and hopefully you can see that as well. What I'm really excited about is the future. We have our Zagreb, Croatia R&D team that developed this product, and I'm really looking forward to some of the other products that they can utilize that technology on.

The product currently, has a black box, warning on it. So it's not supposed to be used for patients that, could potentially be pregnant. But we did, in fact, reformulate the product. And we're anticipating the removal of that box, very shortly to expand the market even greater.

So let's talk a little bit about our 503B compounding business. There's a whole host of reasons why 503B compounding is extremely important to our hospital pharmacy customers. It's a really important service that they count on 503B's to do for them. Hospital pharmacies have very limited resources and staff, and to make things even more difficult for them, they struggle to meet USP 797 and all of the regulations that are required to ensure safety for the hospital as well as the patients.

So the reason why Hikma is perfect for this space or this service is because of what we do when our core business, we know how to aseptically fill. We know the analytical work that's needed to support this business. And we know all about the testing. We can also leverage a lot of the supply chain benefits that we have in our base business to bring the value, in the form of compounding to our customers.

So this is really an area that we're very excited about. The business is growing month over month. And again, just as just another way that we can expand the relationship in the hospital pharmacy with our very important customers.

As we go across the border into Canada. You know, I'm really happy to say that we're really growing very rapidly in our Canadian business. You can see that we're already in the top six. We're going to be in the top five very soon with the significant growth, of 34%, compounded over the last couple of years. And really, the main reason for this is all of the product introductions that Hikma has been able to give, to the Canadian team and enter the market, many of those products also into shortage situation.

So we're taking, relationship that we already have with Canada, Health Canada. That's very good. And making it even better. And again, we anticipate this growth to continue as we introduce more products into the market. That being said, we're going to hand it over to Nassim.

Nassim Rahmani: Thank you Joel. Well, the nice thing of being the last one to present is that I can, quote unquote, all my colleagues. So yeah, we'll start with, with some historical facts about Europe. As Natheer said, Europe was initially servicing, historically servicing US and MENA. So basically Europe was the production site in the Injectables space for US and MENA, because the focus was on these two regions for different factors.

So we didn't have enough capacity to serve Europe. So our only markets back then were the markets where we are actually manufacturing. So we had a commercial presence in in Germany. We had a commercial presence in Italy and another one in Portugal. Other than that, it was literally, nothing. And the reason behind it is the capacity and also because back in the days the economics in Europe wasn't that attractive compared to now.

So what I'm going to present now is basically what we have been doing in in Europe. But the main disclaimer is that the strategic decision to go into the European markets widely has been taken around four years ago. So we are really at the start of our journey in the European market. And we will see in the slides that it's already, like it's already picking up and yet we would expect this to, I mean, this momentum to, to be sustained.

Starting with basically the European markets. So what we can see here is, is the top European, countries in terms of, pharmaceutical markets, so Germany is by far the biggest, followed by France, UK, Italy and Spain. So this is called in Europe, the EU five. So the EU five are the meat of the European business. And then to be fair, EU six is Poland. But then we put Nordics together as four countries. Yeah. So and this is basically the countries where we are present or where we are going to be present in a very short term. So by this we would be covering very soon 83% of the European market. And when I say covering, which means we have our teams on the ground and we are selling directly to hospitals. In terms of also value chain, the fact that we are manufacturing in Europe for the European, market, it's something that is extremely, extremely differentiating compared to our to our competitors.

On the right hand side, we can see the competitive landscape. This is without biotech. So we're talking here generic injectables. And the nice thing I mean the nice pattern we are noticing here is, so you have basically the size of the bubbles is the is the sales. And then you have the CAGR to 2024 and then you have here the number of units sold in 2024. When you look at the top five, the top five in Europe is declining. So or growing like. Yeah, slightly. What does it tell.

So the, the, the European incumbents are declining in the injectable space for two reasons. The first one is the focus on the biologic space. And this is basically pushing them to divest their small molecules asset that is leaving the white space for some companies like Hikma.

And that's why you see, when you look at Hikma, we are the sixth largest as we speak. And in terms of growth, we are among the top growing companies in, in Europe. And then talking about the growth. So we have done 22% year on year. And we believe that this is something that we really can sustain for three reasons that were mentioned.

One of the first one was mentioned by Ragheb. All what we are doing now in terms of capacity expansion, anytime of R&D is going to serve directly, Europe. And the synergies that we are getting, whether from the US market, from our R&D work, from Zagreb and also from the expansion on of our production capacity will serve directly Europe.

And also when we compare our profile with our competitors that are pretty much like not the incumbents but the newcomers and also the Asians. Our supply chain is by far shorter, our reliability is higher. And most importantly, the fact that we are pan-European also gives us some European synergies that our competitors are lacking. So yeah. And then it's important point also to see that the top 15 represents 66% of the of the total. And this is different from what it was in the past.

So with this we will be talking a little bit more about Hikma in Europe and our sales for the last five years, actually. And this is basically what I was mentioning earlier. So around 2021, when the decision was made around COVID, that we need to expand in the European market. So since then we've been having double digit growth, as Natheer mentioned, our agility and our ability to answer to the European needs is quite high. The reason also behind it is that Europe now is suffering from shortages everywhere. So the European market today is really hit. And you can see this in the press. And basically we arrive at a time where basically the incumbents are divesting from this market. And when we arrive, we are having a stronger, supply chain, shorter. And the ability to serve, the market in this time of turbulence. And then, as Bill mentioned in the beginning our aim is to is to be top five, and it's something that is within reach, definitely within reach. And this will be supported actually by three things.

So the first one is the fact that we are adding capacity. So the more capacity we have, the more ability we will have to, to answer to the clients needs. The second one is the territorial expansion, as I mentioned earlier. So we already launched Hikma in Spain, in France, we are launching Belgium, Poland. We already launched the UK and last but not least, the tailored product for the European business.

Our position today is making us very, very close to the hospitals. So literally the feedback we are getting from the hospitals, whether in terms of shortages, in terms of ease of use, is really is really conveyed to the company directly, whether it's R&D, whether it's supply chain, whether it's production and this is basically changing. Changing the way we are addressing the European market because we are directly in touch with government purchasing groups. We are partnering with them in this time of, of turbulence and the R&D work that is being that is going to be made in Zagreb would definitely support this strategy, whether in, in, I mean, basically it's all what Ragheb mentioned, taking product that are today in cold chain and transferring them into room

temperature, taking products that are today, that need to be diluted and reconstituted and put them directly into ready to use or ready to administrate.

And knowing also that Europe on top of suffering from shortage of pharmaceutical products, as you all know, I read in the in the news, Europe is also suffering from shortages in nurses and healthcare professionals. So yeah, we are at the very start of this journey. And I mean, we're very proud and happy with what we have done so far.

But it's important to mention that this is just the beginning. Thank you everyone.

Bill Larkins: So I just want to just do a quick brief wrap up. So, you know, over the last five years we've had really strong growth in this business unit. We've been focusing a lot in recent years around diversification of our revenue. As Nassim was talking about with the growth in Europe, the growth that we have in MENA now with this additional pivot with our specialty business in the US, to diversify away from just the normal traditional base business that we had in the US.

So we're focusing in on that. We've been diversifying our R&D portfolio, as you heard from Ragheb as well, making sure where we're adding some complexity and some differentiation into what we do. We've been very metered in that. So it's making sure that's adjacencies to what we already knew how to do. So it wasn't taking some wild leap of faith into something we didn't really understand, or how does it work. So we've been, rapidly expanding into some new areas. We have, as you saw, a lot more to go, I think, with our manufacturing footprint, our commercial infrastructures that we have in the MENA region, Europe and in the US, and then also the R&D capabilities we have and our BD activities that the strong growth we had for the last five years, we're really excited and confident about the growth for the future as well. So hopefully, that came across for you guys today as well.

Conclusion

Riad Mishlawi CEO

Riad Mishlawi: So it's always, it's always good to, talk about strategy, which is really if you go to ChatGPT and asking for a strategy, they'll give you the same thing. So strategy is, very in my, in my experience is, it's simple. It's similar from one business to another. I think what differentiates you as being a good company is how you execute your strategy and your understanding of the company itself. We're a pharma company, you know, that's something that, you know can be forgotten. A pharma company, operates in a system that's mostly in all the world is a broken system. Whether you are in the richest country in the world or the poorest country in the world. It just doesn't work well. In the US, richest country in the world. You know, the health system, we all know that is not really perfect.

A lot of people probably would have to sometimes choose between getting groceries and, you know, buying incident. And that shouldn't be. This is something that should be very basic to every human being. Egypt, you would go to the pharmacy and you wouldn't find the medicine you're looking for. Germany, second richest country, one of the richest countries in Europe. Yeah, you might find the product and the doctor would give you a prescription for it, but, it's not reimbursed, so you will have to pay for it yourself. So it's a very broken system, very complicated system. You add to it the regulatory burden that you have to have, the quality that you have to maintain, your responsibility, your towards your investors if you're a public company, it just becomes a very complicated system that you're working in.

So going and saying, you know, enhance, leverage, develop, expand all of those things. Yeah. The great but you put it in the context where how you operate. It's a just a different story. It's a very complicated system. And in order for you to do well, you really need to understand the details of how you need to go, what differentiates you from other companies? What makes you strong, what you need to do? All of that is very, very important in order for you to do well.

I mean, as a pharma company, also, you have responsibility. You have responsibility for your patients. And that's very important. People maybe underestimate that. When I used to talk to a lot of the employees in the, in the injectables. When I was head of the injectables, I used to give examples of, of the patients. How many units do we sell in injectables here in the US? 300 million. How many seconds are there in the year? I don't know, 31.5 million seconds in one year. If you make the math every second there are ten patients that take our drugs. And they are not pills. They're not something for a headache or something for a stomachache. They're something for somebody in the hospital that really, most of the time, is that drug save their life. That's a huge responsibility. And you can just do it. You know, if you have a bad pill or a bad, you know, for a headache, you might not get the effect.

You have a bad injectable drug, you kill someone. So the responsibility is huge. And we have the responsibility for the patients. We have the responsibility for the investors. We have to be careful what to say. You are all, you know, the analysts and investors, and we can’t just promise something that we can get you. You will punish us, you'd kill us.

We have that accountability for the investors as well. And of course, we have the accountability and responsibility for our employees. We have so many families that depend on our income, so many families that depend on their jobs, on the sustainability of this business. So it's not an easy thing to go around. So I think whatever we're going to put for the strategy is going to be nice. It's very similar to the forecast that we get sometimes from the sales and marketing. And you don't like the forecasts. Okay. Let's go to the spreadsheet and just multiply that by 10%. And they give you another one year forecast. So it's not about the number is not about the colors. It's not about the tables, it is really about the context. It's about understanding what you're presenting is like believing in it. That's more important than the than the colors or the tables that you're doing.

But despite all that, I think we can say in the last five years we did fairly well and we had a lot of headwinds. You know, if you remember, we've had, tough, tough generic, environment in the 20s, in the early 20s, 21, I believe it was pretty difficult for us. We struggled and, but yet I think with all that, we continue to do growth, we continue to, give some healthy numbers. And for every business, despite all the difficulties, despite all the headwinds, in some cases, we still came out with good, you know, growth from both, top line and bottom line. And I contribute that for I contribute that to the foundation that we have. A month ago we had a leadership meeting in Jordan. We invited 83 of the top employees from all over the world to come and meet in Jordan.

Two days of meetings, we went over a lot of a lot of different things, but the purpose of that meeting was one for everybody to get used to, everyone else, two, for us to kind of, you know, maybe agree on how are we going to move forward? Some of the critical issues. But most importantly is collaboration. How we can create enhance collaboration. What are we as a company with a lot of new comers? You know, we had everybody who had come new to the company to stand up and we had about, I would say, 10 to 15% of those that had, stood up like Chris, for example. So we've had a lot of newcomers to the company. And, we thought that would be a good forum for us to get to know the company, get to know the foundation of the company.

It started in Jordan. So that's why we chose the location with Jordan, and I started with a small story, started the meeting with a small story. And it's a true story, actually. It's about bamboo, and it's about that bamboo in my garden that I tried to kill. And I could not kill. That bamboo tree is probably the most difficult tree to kill, because once you start, you do everything that you can. It will sprout somewhere else. You kill it from that place. You sprout, and fast. In a matter of days you'll have a sprout to spot here. So you really, really can't kill. And I had to find out. How can I do it? Because I was killing it in one side and it goes underneath the ground and it goes in the grass and in the land that it had. So I had to do something about it. I started reading on what kind of poison I can put to kill that tree, but I learned a lot about it.

And one of the things that I learned, I thought it would be a good story to talk about foundation and the fact that some of the bamboo, some, strains of bamboo that exist, they are, they start with the seed. So when you only want to plant them, you plant a seed and you have to water it continuously. First year watering it, you'll be you'll see nothing. No sprouts, no green. You'll be thus watering, dirt. Second year, same thing. Third year, the same thing. Your neighbor is looking at you to say. This guy is crazy. Who is this? What is he? You know, there's nothing

going out there. Fourth year, the same. Nothing happens. But on the fifth year, in a matter of 6 to 8 weeks, it grows 90ft, 90ft of bamboo. It grows.

And the idea was, well, did it take me 6 to 8 weeks to grow, or did it take really five years to grow? And the fact that it did take five years, but what was it doing in the last five years? You know, what was it doing underground? Nobody's giving credit to them. Nobody's saying that you're growing anything. However, what's happening on the ground is building that foundation, is building that infrastructure. No wind, no angry owner like myself would kill it. No wind will make it break. It will sway with the wind. It’s flexible enough and strong enough to grow. And it's growing so aggressively. All that is a product of a good foundation. That is a product of a good foundation. So the more and the stronger your foundation is, the more you are, able to sustain headwinds, the more you're able to create exponential growth.

And that's what we're looking for, that exponential growth that was going to make us grow. And that happens. Once the momentum takes off that happens very, very, fast. Who likes Dan Brown here. Does anyone read Dan Brown. All right. Well Dan Brown is a very interesting guy because he writes very interesting stories. But in the stories there are a lot of facts, a lot of facts.

In fact, in his book, on the cover of the book, every book and I've read all of the books, it says that it's all based on facts, yet the story is all fictional. But everything else he says based on facts. One of the things that I learned from that, and I used to really like his stories and like all the examples that he gave, he talks about exponential growth, and he says, if you take a piece of paper and you cut it in half and then you fold it, and then you cut it in half again and you fold it, and you do that 50 times how big that pile of paper do you think it would be? And it's very intuitive to think, but it will be if you do that 50 times, it will be 150,000,000km high. It's the same distance between the Earth and the sun doing that 50 times. So exponential growth once you start doing it just takes off. That's what cells do. That's what a lot of diseases do. That's exponential growth. Once it starts taking off, it's just very easy for it to grow. So that's what we're looking for. We're not there yet but we'll be looking for that.

This is our strategy, looking at the strategy that we have and looking at some of the details that we really need to look when we were looking at the strategy. So there are yeah, it's great to say, you know, develop differentiated pipeline, but then differentiated has been used. And I know you guys investors here and analysts you read a lot about other pharma this differentiated, specialty. All of that has been used very, very loosely. But we are really serious about it. We needed to have differentiated pipeline. And the differentiated pipeline doesn't happen just because you're writing it. It happens because you have the talent to do it. And if you remember the first year that I started, first thing that we did is we said that's what we need to do. We need to get the talent we brought in. You know, the presidents of both of the divisions that we have, the both PhDs in chemistry. They're both R&D background. They both know that very, very well. So that was really the main thing that we had to do. Enough talking about it. Let's do something about it.

They came in the first thing that they did, they created the team for R&D, that's what they know well, they can do it with their eyes closed. So, you know, the first thing that Hafrun can, for example, you know, first thing that's the first employee that she hired was Chris. So you wanted to grow that thing. So when we were talking about one thing, we need to talk about how to get

there. What we're going to give you the numbers is here's to our confidence. Where are we going to grow? We're not going to give you the numbers. We're going to give you not only to you, to ourselves, to be convinced of how we are going to get there.

We talked about smarter operations, increased output efficiencies. Beautiful sentence. But what does that mean? We keep talking about low cost countries, you know, India, you know, China, low cost countries, local. But you know, if you really think about it, it's not low cost. In the pharma industry and the industry that we are in. I'm not sure if it's really that believable.

I'll tell you the example. For example, we have, in the cost of every unit we make up between 15 to 20% of that is labor costs. Everything else is API, electricity. You know, everything else that is universal cost, no matter where you are, if you're manufacturing a drug in India, you'll pay for the same API that we're paying in the United States. You get it to the same source maybe. So there's no advantage there. Your power, your electricity maybe will have more advantage in the US. But it doesn't matter. It's going to be a fraction difference. Let's call it the same. The power that you need to run the equipment is the same. That's an energy that you are going to also put it on your gross profit.

What else is your cost? Equipment depreciation. We're buying from the same vendor, same price. It doesn't matter if you're in India, in China, or if you're in Europe or if you're in America. Same price. So what matters really? Well, we talk about labor; 18% that we're talking about here. Well, if you take some of the transportation costs all the way from China or India to here, there, that's an advantage to the people that are manufacturing in this country. So what are we left with? 14, 13%. Invest a little bit in automation. Then you're almost the same. So you run it more smartly, you run it more efficiently. You invest in your equipment, invest on automation, and you shouldn't have an excuse why an Indian company would be competing with you. They would be competing with you because they have more portfolio than you, because they are faster than you, because they understand chemistry better than you, but not because they're only low cost.

I don't buy it anymore. If you invest in your operation the right way, if you are, if you know how to run it efficiently, if you invest in automation, the advantage is very marginal between a high quality local manufacturer and between an Indian or a Chinese manufacturer. We might have the advantage there. So that low cost thing is not really working. But what needs to work is you need to define your efficiency, and you need to make sure that you know what you're talking about. When you say, I'm efficient, what does that mean? Less people or less cost and more output. It doesn't matter. It depends on your plant and depending on what you're doing. But you need to really know and understand that.

And of course, quality is a big thing. And I'm sorry, I should have started with this one. You know, and I always say to everybody that we can talk about quality all we want, but quality is inherited in what we do. It doesn't have to be highlighted all the time. It has to be the Bible of what we do.

You know, I give the example of airlines. Airlines don't say fly with us because we're safer than the other airline. It has to be safe. It's part of being safe. It's part of being airline. It cannot just be safer. You just have to be the safest no matter what. And this is the way it is with us.

These are big things. And this is why we had that leadership meeting. Synergies. I believe in operating with three different divisions because they're very un similar. There's nothing really that much in common. Of course, there are some things in common, but the differences are more different than they are similar. And this is why they should be, three different divisions, they operate from, different facilities. They sell to different customers, different regions in some cases. So yeah. Why not. You know, you want to put them together. Then you get a mishmash of things that you focus on what they do. But there are a lot of things that we can do together. You know, we're talking now some synergies that we can identify in R&D.

You know, why should we have a team here and a team here. You know, they're doing the same work. You know, what does it have to have, you know a person that designs labels for this division. And then this person designs the label for that division. People designing a label is designing a label. Why can't we have one team?

And I can go on with a lot of examples of synergies. And you feel it today? You know we talked I think who was it? I think Joel was talking, or Bill, you know, was talking about Kristy, how Kristy, you know, helped them in some of the, injectable products that are being sold on the retail level.

So synergies are there. We had a lot more, I think, protection between divisions. We wanted to operate very independently. And I'm as guilty as anybody else, that would want to have this, because I ran a division and I want it to be independent. I know I feel like a hypocrite standing in front of all the company, and we have to work together. I used to say, don't tell me what to do. Just give me what you want me to do, and I'll do it by myself. But I think, now we have, we are a different company. We're a lot more mature. We're a lot more of a team. It was different before I think. And maybe the reason why is because we were like, different parts of a company. It was maybe a lot of acquisitions. And acquisitions. It takes time until it becomes, a part of the company. And maybe that's why, and maybe the leadership has to do a lot with it, too. But I think we're at a different level right now because I see that it's more, you know, ask for and more done without asking.

Everybody is looking for those synergies, and we are identifying a lot of them. And we are going to definitely, produce a lot more for a lot less. Operating sustainability to ensure we can deliver for our purpose. Of course, this is something that, you know, we always do as a pharma company. There are a lot of, obligations to the society, to the environment, to the countries that we work in, especially we have a big part in MENA where that is extremely essential, you know, access to medicine, the environment and all of those things.

So this is something also in our strategy. And we have the team and we keep looking at ways to, to, to also operate within this. And lastly partnership and this is new. Partnership to us wasn’t really something that we looked so much for. We manufactured everything ourselves. We developed everything ourselves for the longest time. Only until recently we started realizing that we can't make everything, and if we really want to get into the interesting things and learn new things, we have to partner. But not until recently, with new tariffs and all of that, where we started thinking, look, now it's more, an opportunity for us to partner, you know, now that companies are looking to say, well, what's going to happen to my investment that I put so much forward to go to the US now, would I be able to get my investment back now we're saying, well,

wait a minute, we are a U.S. company. We manufacture all in the US. You have the technology. You spent so much money on it. We have the infrastructure to make it. Let's partner. Let's take that technology. We'll manufacture. It will give you some money back. So it's being presented to a lot of companies and a lot of companies are saying, you know what, that makes sense.

Yeah, we would be willing to do this. We could de-risk all that investment that we have. Let's partner together. That would be a different type of partnering that they're used to. We're used to I'll make it. I'll give it to you. You sell it. Give me half the profit. Now it's more of I invented it or I have the technology to make it. I will transfer the technology to you. You'll make it, and then you sell it, and then we'll split the profits. So we will benefit a lot more, because not only that, we will be able to get the product, but we will be able to know how to make that product. And that knowledge, of course, will help us develop our own, will help us to expand our portfolio.

Nothing goes without, risks, of course. So we try to identify them. And nowadays these bubbles are growing and growing and growing. But, the risks are not the problem. You know, we'll always find ways of how we need to go around the risks and in many cases, maybe turn those risks into opportunities. The problem is understanding them.

That's where we are today. They're not clear. And that's why they are risky today. But I feel that once this is clarified, we really can turn them into more opportunities than risks, especially with the position that we are. We are a good operator. We are a global company. We are operating in every continent there is, and in the US where it matters the most.

We are really, really, really big and we are getting bigger and we are investing more and more and not because of this administration, because this is our philosophy, our philosophy. Manufacture closest to the market that you operate in. This is why we have so many plants. We have 32 plants. And yes, can we boil them down like what Sandoz did went from, you know, 85 to 15? Yeah, we can do that. We can say, okay, all the injectables can be in Portugal. We don't have to have six plants around the world and all the orals for, for MENA can be here and all. But our philosophy from the very, very beginning, operate in the, in the, the environment that you market in for many reasons. One, you will be part of that environment, part of that society. You will be respected by the regulatory. You will understand your market better and you will be, you know, you will be an American company. You will be an Algerian company, you will be a Saudi company, and you will be treated like a local company, which gets you a lot of advantage.

That was the philosophy in the very, very beginning. It continues to be. And that's why we are in the US, and we manufacture more than 80% of the products that we manufacture in the US, or sell in the US is manufactured in the US. That's, you know, paying off now. And it paid off During Covid time. If you remember supply chain was all broken. We had the best years when everybody else was struggling. Why? Because we operated locally. We had the right inventory and we had the right locations.

So in this case here we have tariffs. Everybody's asking about tariffs. Everybody asking about this MFN pricing which we still don't understand it. But you know we don't know who are we comparing things to. It is a term that is used today, but we don't know if that's going to be compared to the Europeans, to the Canadians to, I don't know. We don't know. Of course, you know, being domestic manufacturer, being, you know, with the complexity of supply chain today,

I don't know if you follow or read some of the articles, but right now, supply chain shipping from China and shipping around the world has increased substantially. And the reason why is because not too many shipping is happening. A lot of the shipping companies are cutting vessels, vessels are half empty. So of course with the half empty they charge you double. So now it's becoming complex again to do supply chain. So how great it is to be, you know, operating in the same market that you manufacture in.

And lastly, when there's uncertainty and we've seen that before, there are shortages. And who can really capitalize on shortages more than the people that are closest to those shortages, closest to when they happen and have a very efficient operation. And I think we do. I think our operation is very efficient. We've proven that during the times when we had shortages, we had introduced many products, in these environments, we have done well, and we were able to always turn on a dime when we had to and introduce products to the market.

So these are yes, there are uncertainties. There are, definitely risks. But if we look at them in a different way, if you look at them at half full, not half empty, maybe we can turn them into opportunities.

We talked about this and you've seen it in the in our press. This morning, we wanted to give some, mid-term guidance. We went to, the 6% to 8% [revenue CAGR), 7% to 9% [EBIT CAGR] in the next three years. We did give also some kind of indication to the five years. So, you know, you wonder, why do you give three years and five years? Why don't you just give one number? And the reason why is because we can see the three years clearly. The five years we can do better than that. We are investing so much in the facilities that we have today, in the operations that we have today and the business development that we are putting. You know, the teams have told you $500 million in the next five years in operations and the plants $500 million only, and the injectables $500 million in this, division in the division. the $500 million, just to be clear, is not all from our pocket. Half of that is coming from the CMO client that we have. So they're paying for half of that. But still, it's a lot of investment in our facilities, and all of that is going to have to be translating to steeper growth. We cannot expect the growth to continue the same way that we've had for the last three years.

But that's the growth that we had for the last five years, and we think this is sustainable for the next three. But I think all these seeds that we're planting and have been planting, they need to accelerate the growth for the next three years after that. And that's why we had to give the two guides.

So we also wanted to kind of look at and show you so many things, of the things that the team has told you about. You know, we talked to you about the Xellia portfolio, the expansion in Europe and what we can do there. And once we expand our capacity, Europe becomes, it's been growing very nicely, and we have the opportunity to grow even steeper. One of the things that I think maybe, Nassim had, touched on, the European countries are very excited that they have a European company actually selling them products, because right now it's Accord and it's, Aurobindo, Doctor Reddy's, mostly Indian companies that are selling.

And what happened with Accord two years ago, if you all remember, when they had this big issue, there was no cancer drug in the market in Europe, and it was a big issue and it taught

them a lesson. You're going after the low cost, the very, very low cost. You can, but expect the risks of being out and you'll be out totally in all of Europe because Accord had all the cancer drugs and mostly almost all of Europe coming from India, they got in trouble by the FDA. They closed the facility and there was no drugs there. You know, vancomycin RTU, we kept talking about it, a great product, one of the very few products that we ever had that has patent. You know, we feel like, wow, we have a product that we don't have to worry about every year. We don't have to worry about competition coming in… Why did they grab this from us? Are they going to come? Who's coming? Is this coming? Are they coming? This is our daily life. Who's going to come and take some market share from us? How can we protect ourselves? Well, in this case, we're the only ones in the market. This all depends on us. Can we do good? Well, for sure. This is a product that, you know, everybody has explained to you, is used by every hospital. It is very complicated to reconstitute it. People depend, hospitals depend on compounding centers. Once we have this approved, compounding centers will no longer be allowed to make it. Because now you have an NDA that's approved by the FDA. So there's no reason why compounders need to do it. So we're very excited about that.

Zagreb is another thing that we're excited about. We never had this presence in R&D. We keep talking about R&D. We could talk about differentiated products, we keep talking about this, but we really never had the talent or we never had that big bulk of people to say they are competent enough to take us there. Well, these guys are not only competent, they have proven that they're competent. They really came up with this product that we're talking about and many other very nice products that they're working on. Can we take that one and leverage it to the rest of the rest of the company? That's exactly what we're trying to do.

Upgrading Bedford is something that is very nice for you to see tomorrow, if you go up there tomorrow, it's a beautiful facility. It's a huge facility. You'll probably walk more than you walk today. But you will see how this progress is going. You know, people have been here and to Portugal in the past and saw Portugal, you know, five years later, you know, you'll be, very happy to see Bedford today, I think come back in 2 or 3 years and see how it is when it's operated

Expanding the MENA capacity. We have Morocco, Algeria, we've been building plants, adding on what we already have, adding on the mber one, business in MENA and ad yes, in MENA we are number one or number two in the entire MENA. So we're building and adding to that. And we have very big aspiration to be. Also we are number one in Saudi Arabia now, but we are really building and adding more and more facilities to be really the number one, in that in that entire region.

Hikma Rx, you know, we told you about a lot of that, too, and I don't need to go over it. But you saw it yourself. One of the biggest things that we have going here is the CMO and R&D, I think those are the two main things that we have. Of course, operations keep improving, keep adding. And that's a given.

We keep adding around $40 million of capital expenditure here. From Hikma to the core business. This is, this thing is going to double or triple in the next few years. Now, with all the

CMO now, asking us to build and expand and do more and bring more machines to accommodate the needs

And finally Branded, this is a the oldest business that we have, the most sturdy business and the most different business than the rest of, the rest of the group. We're more branded. Branded means that we have our own name, our own brand. Although they are generic, some of them are generic, but we have our own, detailing team 2,500 sales, detailing the rest, for all MENA.

Well, how do we get to the long term? We said let's do acceleration from the three years to the next three years. And, we got to, a whole number $5 billion in 5 years, with a nice ring to it. Hopefully we can get more than that. But how do we get there? Well, we talked about a lot of those things, but these are some of the, you know, milestones that we're looking at.

We need to start launching complex products. We're talking about launching we're talking about developing it now. We talked about putting the R&D team together. We're talking about Zagreb. We're talking about what Chris is doing and what Ragheb is doing and all of this. Well, three years from now, we should be launching, though, we should be able to talk about launching epinephrine and not submitting epinephrine. Right. So these are the things that we are going to be doing.

Partnering. We talked about these examples of partnering. Can we take technology from our partner and transfer it here? Yeah, we can start working on it. But now beyond that we're going to actually start benefiting from it. Investing in R&D. Also another thing that would be benefiting from we're starting now to increase the benefit, the investment, we need to get something back.

And we think that unfortunately this business that we are in this is like the Christmas tree business, you know, you plant the tree today so you can sell it in 5 or 6 years. We have to always think ahead. We have to always think in 5 or 6 years what's going to happen then. And this is the case here. We are going to start investing in R&D because in 3 or 4 years after we develop, after we submit, after we get approval, and then after we launch, we get the benefit.

It takes a long time that cycle. We can't just say, I'm going to change the company like this. It's going to take a lot. After you put the strategy together, execute on the strategy and then get the benefit, that's three years from now.

And so on. Expanding capacity. We have talked about that expanding geography. We talked about Poland. We talked about some of the territories that we have in Europe that we can expand to, we talked about CMO. CMO is becoming a big thing. You know, Natheer was saying, yeah, CMO typically we had it as a capacity filler. We have empty capacity. Let's just rent it out so we don't, you know, we don't have a facility running half full and incur a lot of the cost. But now we have proven that, you know what? We're good at it. You know, we're good at CMO. Companies trust us. We don't need to be a CMO organization. We're not going to go and shop for everybody. But if we partner with 2 or 3 large companies that need high quality, reliable partner, we probably will be the first one they will choose. So let's leverage that. Let's go. And we had done this very successfully here. And we think we can do it in the injectables as well. We've done it in the injectables as well. But you know we need to add to it as we increase in our, available capacity.

And finally, the compounding business, growing very nicely, we have today we probably this year will be more than double what we had last year. We are finally getting the momentum. Again, it's like an exponential growth. I think in the next five years this is going to be a substantial business. Within the business that we have.

And, that's all for me. I would invite maybe Hafrun and Bill to come to me here and answer any questions that you might have of your own?

Start Q&A

James Gordon: James Gordon, JP Morgan, a couple of questions on the on the medium term guidance. As much appreciated. Maybe the first bit was. So should we think that the guidance is going to be fairly linear, or is it quite backhand weighted in terms of 27 versus 26? Because if I, if I try and back it out, I think that the group level you done about 5% growth. But then you'd have to do more like high single digit growth if it was the same in 26 and 27, but then Xyrem, a bit more competition. Could it be that you've got to do double digit growth in 27? Maybe that's the first question.

Riad Mishlawi: Yeah. Well, you know we thought they were going to catch that. So. So yes I think 26/27 is going to be steeper in growth than the because exactly what you said. But what we, what we feel that there are a lot of things that will be clarified in the next two months about, the business itself. So this is why we did not want to jump there right away. We have, we have the contract manufacturing to start with. There are a lot of things that, has been added to the original contract that we really still don't know how much of a result that would be. We have, Xyrem, as you said, that, you know, we are trying to see, is this going to be now going on our own, or can we, see if we can continue doing what we're doing with maybe a better, deal with, with the with jazz?

I think, there are a few things, you know, talk about, the, the the bags, for example, the, the, Viacom, us and ready to use that we talked about are we going to get the approval in July. Are we going to get the approval in December? Again? That depends. So there are few things that we don't know exactly when they will fall. But I think all of those things that are going to contribute to a steeper growth in the next in the last two years. And so it will be a little bit, starting slower. But I think that will adjust. And, you know, to get to the numbers that we are promising that we would get.

James Gordon: If I understand correctly, 27 would grow faster than 26. It's not necessarily that it's going to be linear. It would be more back end weighted.

Riad Mishlawi: That's that's right.

James Gordon: And then maybe just the other 1 or 2 asks then would be in terms of, what is assumed, some elements of the guide. So what is that assuming in terms of of compounding pricing, M&A and have you put headwinds in or in our not.

Riad Mishlawi: Well, we have we have in our business plan some of those effects. Again, we need to continuously look because as you know, from two months ago to now, you know, there was a lot of changes in the, and currency, but I don't think that would be significant. You know, that usually we get we absorb those things, and we've had this before, but the fact that we are a US dollar based company and most of our sales are about two thirds of our sales are coming out in the US dollars and some of the Mena are pegged on the dollar. So we, you know, any any changes to the currency is yes, in effect. But it's not really a drastic that would change the business plan.

James Gordon: And so I just the final bit of this is but so is it assuming that pricing stays as it is or the tariffs come in and then prices go up a lot, or what is it assuming.

Riad Mishlawi: That no we haven't assumed tariffs. We, we we we just put it there as a potential risk. It could be, an advantage. It could be nothing. You know, right now we really it's not very clear. It would be unfair for us to assume. We did assume, I believe, 4%. Right. And inflation, we did assume because, most of the most of the product that we get through materials for most of the product that is made here, we get materials for from the US through agents. And some of that originates in, in India, some was in China. So we assume that this is going to increase and maybe it will be absorbed by the three parties, by the agent, by the manufacturer and by the customer. And we assumed about 4%.

James Gordon: For the pricing. Pricing for the overall generics just stays as it's been for the last.

Riad Mishlawi: Year without pricing. And still, as we assume, the same way. Thank you.

Alistair Campbell: Thanks. I think that's Alister Campbell from RBC. Just a couple of questions for me again. So, the guidance, the sort of mid-term guidance, we've got operating profit growing faster than sales, so implies some kind of margin improvement during that period. So obviously it's not divisional guidance as group guidance, but I wonder if you could help us understand, you know, what mix effects sort of help or hinder margin over that time period.

Bill Larkins: I mean, compounding is expected to grow. That could potentially be a headwind on margin whereas not compounding. So where you see ammo could be a headwind compounding becoming profitable as pushes and pulls. So could you help me understand how that margin progression happens and why you're confident that you actually expand the margin on a time frame, and then maybe thinking about the 5 billion 2030, just a sense of you sound comfort you can get there is that largely and almost entirely based on what you can do organically, internally, or how much that is going to depend upon, you know, a degree of activity and external, growth.

Riad Mishlawi: Yeah, sure. I'll start with the last one. Am I confident about this? Yes. I'm confident and I think, one of the reason why I have this confidence is the fact that we have been investing in the business, significantly. So I feel that investment is going to have to give us some returns, you know, 5 to 7% of investment in both capital and in R&D about, you know, almost $2 billion if you if you combine those two together, that's a lot of investment that we, we will be making in the next five years.

So we think that this is, unprecedented. And it should give us an unprecedented, type of, of, of acceleration in growth. So, yeah, I have the confidence. Now, what would, why would we be, you know, more profitable and, the next three years for our, for our, three year, there are a lot of things, as I mentioned to you, all of the stuff that had mentioned to you when it comes to, vancomycin ready to use when it comes to the CMO contribution, expansion of our capacity, which, which is going to create, also expansion in CMO all that will be happening in the next three years. And I think all of those things that I had mentioned are, usually higher margins than the average, products that we're selling. So we have that confidence also that we can get that, margin, a little bit, accelerated than what we usually have today. And it's not by much. It's only we're talking 1% here.

Victoria Lambert: Victoria Lambert from Berenberg. I just wanted to ask on the generic GLP one opportunity in Canada because you've been one of the first to market, for your liraglutide. So just wondering, are you going to be able to be one of the first to market in Canada? And, I think you mentioned previously working with partners. So that's the first one. And then just to get a better sense of the epinephrine, the potential size of this, product for you guys. And would you be the only, product in a nasal, format? Thank you.

Hafrun Fridriksdottir: Maybe I can take that. Yeah, I can take that. So there's already a nasal spray on the market, both here in the US and also also in Europe. It was launched, in end of end of last year. I don't think we are willing to give exactly what we are expecting from from that product when we when we launch it, it's it's not necessarily exactly the same, product as we will be filing and, and launching within the next, let's say two years, but it's a similar product. But you can of course, look up what their forecast it is because they have been quite public about that.

So so I don't think we can say anything more about that, but, well, maybe you can take the Canada.

Bill Larkins: Actually, I'll probably pass that maybe to Nassim or Joel.

Nassim Rahmani: Yeah. So the question was on the liraglutide, actually. So the, the the right for the liraglutide for now, only for the United States.

Hafrun Fridriksdottir: It was for all the LP ones. Do you have any other CFP ones with your planning to launch in Canada?

Bill Larkins: So yeah, I prefer I made on this one. Basically there are things that are ongoing, but, I don't think we can communicate on anything.

Riad Mishlawi: Well, we can say that we are not going to be the first ones in the market in Canada.

James Vane-Tempest: James from Jeffrey's, thanks for taking the questions and sharing your vision with us today. I'm kind of firstly on the CMO business. I'm the Hikma franchise looking to have more than 20% CMA by 2030. What was that last year? Just to give us a sense of the scope for improvement.

Hafrun Fridriksdottir: Was 15%. Something like that. Your guess was around 15%, Michael. Okay. So I think it was something something around that size or slightly less. Sorry. Okay. Sorry. It was around 10%. Around three, $100 million or something like that.

James Vane-Tempest: Thank you. Is it possible to have equivalent numbers in injectables? Because I know you've kind of had that activity before, particularly that's, an area of growth going forward.

Bill Larkins: Yeah. So I think, right now we're probably around 7% ish. And CMO is 8%. Okay. And I think, we need to really understand better the capacity that's coming online in, in Bedford. And how much of that lie capacity is going to be available to sell. So it's a little bit of an open

question now, but I'm expecting probably have CMO somewhere around 10% of overall revenue.

James Vane-Tempest: Thank you. And, and in particular, I'm interested about fill finish because I do understand in the industry that's a very profitable, you know, kind of activity and is where perhaps there's, you know, capacity crunch in the overall kind of value chain in, in third party services. So I'm just sort of wondering, you know, what the opportunity is in fill finish in particular. Why perhaps it's not more than 10%.

Bill Larkins: Yeah. I think it's probably not going to be more than 10%, because I think we're going to utilize most of that capacity for our own products. But we, you know, we will look at the economics if there's a, you know, a better, a better commercial, opportunity from a CMO and trade off from our base business. We'll look at that. But I think, look, we think we're going to consume a large bit of that, that, that like capacity ourselves.

Riad Mishlawi: And it all depends on the value. Right? I mean, there is a film finish where you can do inexpensive commoditized products and you can do the biological product, and the return on each of those is completely different. So to take remdesivir, for example, remdesivir, our margins were in the 90s, while, other products might be much, much less than that.

So it really depending on the opportunity, depending on how fast you are in the market, depending on the product value. So all that takes into account, right now, I think, for Bill, Bill's we have this capacity is coming online right now. We are, haven't really started recruiting, customers. I think we will be close. Maybe a year and a half to two years. We're going to start very soon. Recruiting. So until now, it's not very, very clear. But we should be definitely significantly better than we have today.

James Vane-Tempest: Thank you. It also sounds like you're looking for relatively fewer partners to get to the more than 20%, rather than a sort of broader CMO, activities. In your closing remarks, if I guess previously, you are using sort of spare capacity to maximize utilization, perhaps come from a transactional nature, obviously kind of broader, you know, CMO is more sort of relationship driven, where you may need more spare capacity to react to kind of search requirements. So how do you plan to kind of maximize utilization with more of the the business coming from third parties?

Riad Mishlawi: So this has been an internal debate that we have. The debate is should we make an organization, an independent organization, organization, call it CMO organization and, reserve capacity for it? In some cases we say maybe that's a good idea. And in other cases we said, well, you know, things are not clear, right now. We don't know if you want to reserve

capacity because you the last thing that you want to do is have capacity that's a block to a client. And then you say, sorry, I need it. I cannot give it to you any longer. These type of things, as you said, the relationship is important. Your reputation is important. Your relationship with the customer is important. So when you promise something, you really have to deliver. And so this is why we're very hesitant now to over promise.

But the idea of creating an independent and, more of a, contract manufacturing unit is, is something that is being debated internally, and we all might end up doing that. Or, you know, we will let you know to see how we do it. But definitely contract manufacturing has been on our mind. I think what we what you saw here and what could happen here, could happen also in the injectables and has happened in injectables before. It is something that would be a very good pillar of growth. And, we should definitely be considering it to see how we can maximize on it.

James Vane-Tempest: Thank you. My last question for, hanging on if I can is, we sometimes hear from other, generics players that complex generics, it's hard to get paid for innovation. So perhaps I just want to stick to kind of simple generics. So, you know, thinking about a value out of medicines in particular. And you know, what gives you the confidence you can get pay for your innovation and hard work? Thank you.

Hafrun Fridriksdottir: Yeah, I think it is, you know, I think, for example, if you look at, if you look at, for example, respiratory products, clearly they are much, much, much more sustainable than some of their more simpler generics. And what, what we have also been looking into is to develop some novel, novel nasal product. And we have actually, at least few of them, in development now and under consideration.

So, so I think, I mean, that's an example of what, what that could be is, for example, if you take an injection and convert that into a nasal spray, use the same molecule. And of course, it's much easier administration, especially if you have some very serious disease where you need to get that effect immediately. So so I mean, that's exactly, for example, what's happening with, with epi. That's technology, that thinking was put into into developing that product.

And we think there are other opportunities similar to that. And of course, if you if you manage to be the first one, if you managed to do it right, and if you manage to get it on the market with the right effort, then we believe that that's a significant opportunities in in products like like that. In my mind. So yeah, so I strongly believe that we will get paid for the more for the more complex complex product.

Allistair Campbell: Hi, Allistair Campbell from RBC. Can I ask a bit more about your RTU platform? I mean, I think VancoReady sounds like it's got a very important place in the markets. Strong differentiation. I could fully understand why that could be a valuable product. But if you look at the other projects within the RTU pipeline, do they also have sort of strong differentiation and a very strong use profiles, or is Vanco kind of the the star of that particular pipeline?

Bill Larkins: So I think Vanco is is clearly a star on its own. I think because of, you know, what Joel was talking about around sepsis and amputations and death. So, you know, this one has the real world situation. But we see this, in, in so there's a, there's a, this nice through line, I think, between our compounding business and, and this RTU.

So we look at opportunities, we get a lot of feedback from, the health care providers around what it is they need, what what are their pain points. And we're leveraging that then to say, can we make a 5 or 5 v two out of this? And if we can, what is the pathway for that. How expensive is it?

And if we can't then we look at it for our 503B business. So we're kind of covering off all of these opportunities across both parts of this business. But we're seeing a lot of these, these types of products and the benefits. And I think the reason we also have this specialty sales division is to be able to go out and speak about these features and benefits and what the hospitals save. So some of them are morbidity, like some of them are more about savings in hospitals. And so, you know, Vanco is a for instance. But there are other that fit in that same bucket around. We saw huge uptake in rural hospitals. And we we started to really kind of probe into why rural hospitals. And it's because they don't have a pharmacist on the weekend.

And so if they had somebody that came in with sepsis, they had to call a pharmacist wherever they were, they had to travel into the hospital, compound this product to get it to a patient. So they they had really dramatic uptake with us because it's like, I don't need to have a pharmacist and I can have this on a shelf when I need it, I have it and there are other products that fit into that same category where you don't have to have somebody in on a weekend to compound it is available. It'll be available. They can sell it immediately.

Seb Jantet: Thanks, Seb Jantet with Panmure Librium. So everyone has a question on the Hikma Rx business. You hopefully give us some longer term targets for where the CMO might revenue might get to. But I'm thinking more about kind of just getting the balance right in that business around quality of earnings. So if I think of your your white tablet business in the new, more differentiated products, what might the target mix be for revenue from those sides of it?

And in a similar vein, if I think about smaller products versus larger products, where obviously there's a bit more risk on the larger products, how how much concentration would you want to have in your portfolio if you were trying to get the business to where you'd actually like it to be?

Hafrun Fridriksdottir: It's a good it's a good question. Of course, I think to today, I mean, around 60, 60% of our revenue is coming from, Kristy, 5 or 6 products, something like that. So, so, so that's of course, not necessary. I mean, how we want to have the business moving forward. We don't want to have all this risk in those, let's say five, six, seven, seven products. So we would like to have it more balanced. And as soon as we start maybe to launch more of those complex products both in nasals, inhalations, extended release, solid orals, I think we will come to that,

that balance. But I still see that the simple tablets, simple capsules will always play a significant role in this business. And I actually have a strong belief in those simple products as well.

And if you for example, look at what's going off patent for the next, let's say, ten, 15 years, the majority of that volume value is actually coming from, solid orals, simple tablets, simple capsules. So I think it will they will always play an important role in our business. But of course we want to have it as balanced as humanly possible. So we are not taking a huge risk in one product. But this in some cases, it's also really, really good to have new products which are very strong and and there is a low competition. So, so yeah, it's maybe it's not as balanced as we would like to see it today, but I think when we really start to see the, the return from our investment, let's say two years from now, then I'm hoping it will be more balanced and more stable, but I like I like the white tablets, just to be honest.

Riad Mishlawi: Do you think with the addition of or the increase in the CMO, you will have it more balanced?

Hafrun Fridriksdottir: Yeah, that's that, of course it will be. But we have our target. There is around 20%, maybe 25% of our overall revenue from few clients. Then then it will always be a risk in, in that business as well. It will be risk in whatever business you have. But, yeah. We will reduce the risk. I mean, if you have more eggs in the basket.

Seb Jantet: And Bill, on the biosimilars. I mean, historically, you know, you've kind of wanted to partner with people in that space rather than going there directly. You know, obviously, we've seen within the group much more of a kind of focus on R&D and taking control over R&D. Does that change your strategy there was that still an area where you're evaluating and thinking, you know, let's no, let's not dive in yet.

Bill Larkin: Yeah. So I think for us, as we mentioned, we have two in the US now. We're looking still strategically on partnerships. And in biosimilars. It's not something that we would do internal development on ourselves.

Victoria Lambert: Just to follow up, Victoria Lambert from Berenberg, I just wanted to check if, the previous sort of, targets you've given for base profitability still hold. So I think you said previously $100 to $120 million in the generics business. That that seems a bit low, given you guys have done, 160 million plus over the last 2 or 3 years. And then for the injectables business in the mid 30s.

Riad Mishlawi: Well, I mean, we reiterated our numbers in April, and I think we will stick to it. So, we'll giving you now medium so you're going to have to put that in the model I guess. But look, you know, I think, we've been doing well and, and, expanding the generics business over the, or the Rx business as we call it now. And we have more and more opportunities. I think the CMO definitely going to help. We are you know, in the injectables also, we have a lot that we're doing and, so we we're confident that those numbers, you know, we will, you know, meet those numbers and the promises that we have in the for for what we reiterated in in April.

Susan Ringdal: Maybe I think we could clarify that for the generics, we do feel comfortable that the profitability of this business will be increasing over this medium term period.

Seb Jantet: Seb Jantet, Librium again, just one quick clarification on the targets then. So, just want to be clear, are they excluding any contribution from acquisitions, the revenue growth rates. Because obviously there's a bit of acquisition growth in 2024 and then 2025 as well. So it makes a difference when you're looking at the maths and the hill to climb.

Riad Mishlawi: Yeah I mean it depends when we what what we say when we say acquisitions. You know part of the BD and part of acquiring products and part of, you know, small bolt ons type of acquisitions will continue. This is part of the business. Are we going to have any transformational thing that is going to drive that growth? No, this is not what is counted here. In the next five years we said that it will open. We're going to be looking we're going to see, it's going to be a number of bolt ons, number of products that we're going to acquire, a number of BDs that we're going to do. If we stumble across something that we think is worth buying and might be transformational.

Do we, have we accounted for it in our plans? No. But can we use our balance sheet for to meet our numbers? Sure. We will be using it every day.

Jame Gordon Thank you. James Gordon. Does the the guidance just assume CDMO work you've already signed or actually allows for you the fact that you have some spare capacity and you're going to not sign significant further CDMO contracts.

Riad Mishlawi: For the three or the five?

James Gordon: Both of them.

Riad Mishlawi: Well, we're for the five years. We're optimistic definitely, that our current CMO, we will be signing more as Bill is saying that we have now, huge capacity coming in. I think that Natheer showed you we're going to triple our lyo capacity, the lyo capacity is what everybody's been seeking. Lyos are a little bit short in availability in the world, a lot of it has been taken by the biosimilars.

We see a lot of people coming to us, and especially that those lyos are going to be in the US, and a lot of the big, companies that have invested heavily in, the biosimilars, they're now very nervous about, the risk of tariffs and all of this. And they've been calling us as we speak. So we think the opportunity is going to come to us. We're going to choose how much of that we're going to take on. So definitely we'll be signing more for the new capacity coming in.

James Gordon: But so should we assume that for out to 27 it's basically what you've already got signed but going out to 30 you're doing some further deals as well.

Riad Mishlawi: Up to 27 to 30. Yes. It will be significant more.

James Gordon: Maybe one of the follow up, which was just I think on the slide that was talking about, generic Xyrem. It was talking about the market growing, but was that saying that your sales could actually grow or I think the market's growing, but your I previously suggested you're anticipating more competitors coming in as well. So was that a read that you could actually grow or more just that the market grows, but you're not necessarily going to grow.

Hafrun Fridriksdottir: Yeah. Why don't you.

Kristy Ronco: Sure. So the market is what I was referring to when I was speaking. But I do believe that there's opportunity for, you know, if that overall market is growing, then our piece of the pie that we will continue to, manage and supply for, gives us a larger opportunity as we think about the years ahead. So that's, that's the way we look at that's our market.

James Gordon: Because I think, I think the market as in the financial market though of Xyrem as a headwind, as in your sales is going to go down next year because there's more people coming in. But is that maybe not right that that it might not be a headwind? Actually, it could be a growth driver.

Kristy Ronco: we are not providing guidance at a product level, but I do think that we continue to see sodium oxybate as a positive contribution to our to our book of business.

Riad Mishlawi: The story is that we have options, and we will choose the best option when we get to the time that we have to choose.

James Vane-Tempest: Hi, thanks for taking my follow up. It's James from Jefferies again. The 503B business. Recognize it's a very sort of slow burn up before it takes off. When I read that in your closing remarks, you gave the example of paper. But, you know, whether it sort of does that or not, we have to wait and see. But my understanding this is a, you know, roughly $1 billion market, right? And it is kind of growing. So I'm just trying to get a sense of scope more and say, but by the time you get to your 2030 aspiration, you know, could this be a $100 million business? Is it still like a $50 million business? You know, could it be a lot more than that?

Can you give us a sense in terms of where you see that opportunity and how much, that can contribute? And then my second question is, I guess just for the site given we're here, you know, I understand it's, you know, 80 acres, you know, you've got a lot of great projects which you've shown us today, obviously need to, to deliver, deliver on those. But in terms of the potential of the site, you know, how much more, you know, scope is there for extra buildings and projects, etc. and, down the line, thank you.

Riad Mishlawi: I'll say a couple words about, compounding just to the consistent message that I've been saying. And then I'll leave it to to Bill to talk a little bit more about the details. It's it's the compounding business is a business that as we speak today, it's changing dramatically. And if you follow the compounding business, you'll see that the FDA's attitude about this compounding business is changing. They're expecting the standards and, you know, the compliance to be the same as in the core business. So, testing the raw materials, testing the impurities, doing the small studies, sterility or microbiology should be the same as in the core business. So a lot of the compounders are struggling to meet that. And if you read about it, just almost everyone is getting in trouble by the FDA for either 483s or warning letters because of those things, which in a way creates an opportunity for us.

How fast, how big can we grow? Well, the business is estimated to be around a little over $2 billion and maybe more. It's really depending on how can you convert the hospitals from not compounding themselves and rely on you to compound. Now, hospitals don't want to compound, and especially now because the FDA are asking them all of the requirements that they're usually ask us in the core business to do, and they're not really experts and doing validation for their filters and, doing, you know, smoke studies and training the employees and qualifying this and qualifying that.

So it's a burden. The problem is that they don't trust somebody else to do it because they've gotten hit by or they've gotten bit, as they say, by a lot of, vendors in the past, as you know, a lot of them had gone out of business. A lot of them had recalls. So do they trust to depend on somebody else?

Because if you take fentanyl, for example, it's used in heart surgery. A bag of fentanyl costs around $20. A surgery costs, maybe it will bring in about $600,000 for a hospital, and a hospital will not postpone the surgery because they don't have a bag of $20. So to them, sure, it might cost them double that, but at least they assure that the surgery will not be postponed.

So once they get somebody that they can trust, then they would have all the, you know, there would be would open arms to say, please make it for me. We are working towards that. How fast can we get that? We had done a very good job so far. We've had, enrolled a lot of hospitals, but you would have to go one by one, door by door, and they are going to test you. And once you pass that test, they're going to trust you. So it takes a long time. But as we see it today, we are growing. We are the most trained. I would say, to have, much more, compliance compliant, operation than somebody that is just a pharmacist that doesn't know the core business specialty. Especially that most of the products that we compound is manufactured in our own facility in Cherry Hill. And Bill, do you want to add to this?

Bill Larkins: Yeah, I think there's there's a maybe surprisingly, a quite a long sell cycle for a lot of the hospital systems to get to 503B. So a lot of them we have to fill out questionnaires. A lot of times they'll come on site, they'll do their own audits of the facilities. So there's and then that goes through committees within the hospitals to be able to get registered as a 503B supplier for them.

So that process takes a while. We've been doing a good job of onboarding hospitals. We've had a lot of tours of the facility. The facility shows really well. As Riad said, I think one of the things that we continue to to discuss with, the potential customer is, you know, we have our core business where we're an expert, you know, kind of experts in this space. And that's what sets us apart from from others. And then we really see the the ramp up really starts to come exponentially. So a lot of times once we onboard a customer, they'll buy one SKU of something and see how we perform on that. And do we perform right? Do we do they get what they need or they get it on time and then they start to add more.

As they get more confidence, they continue to add more SKUs. So we're seeing both the onboarding of new hospitals and the ramp up and the number of SKUs that they're ordering. And so we're starting to see this significant growth in that business kind of month over month. At this point.

Hafrun Fridriksdottir: Okay. So you asked if we are planning to expand this site more than what we are doing today. Wasn't that the question?

James Vane-Tempest: Not are you planning to because even as you got a lot of your interest.

Hafrun Fridriksdottir: Is the possibility, I think it is a possibility that, yes.

Mike Balog: So we do have about a five acre greenfield space in this campus that we've kind of reserved for the project to be named later. That's not defined. However, I will say our full goal is to fully utilize the existing space as is, the expansion that we're currently existing, I think is probably a good model for the future. Where we talked about partnering with fewer, better partners? Were there willing to co-invest with us, to to offset the cost of the CapEx, to give us additional capacity. We also have some technologies that we're doing less and less of, like blistering technology for one of our partners for Europe. We're doing less of that. So we're redeploying those areas within our facility to support unit dose and other things. So better utilize the existing facility is always our first priority. If we find the right partner, will expand as required and have them offset the CapEx.

Riad Mishlawi: All right. I think, I hope that you got what exactly what you came here for. I know you traveled a long time, so thank you very much for for coming. Thank you very much for being patient with us. Half a day of presentation is not easy. I hope the food was good and dinner was good last night. But I really hope that the message that we wanted to convey to you, it was done correctly and and you've gotten all the information that you needed. And finally, I should say, you know, I've been little more over, than a year now as a CEO. I'm very excited about what we have built so far.

But mostly I'm excited about what we will have in the future. I think we are, the better team than we've ever been. A lot more tighter, a lot more focused. We got to the level of details. That execution of a strategy become simpler. Everybody knows where we need to be. So. And we have the right talent, and we keep adding more and more talent.

So I'm excited about the future. So thank you very much.

[End of Transcript]